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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

JUDITH E. CHAMBERLAIN, et al., Plaintiffs, -vs- THE AMERICAN TOBACCO COMPANY, INC., et al., Defendants.	)	Cause No 1:96CV2005

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

PHYLLIS SMALL and DENISE FUBINI, individually, and on behalf of others similarly situated, Plaintiffs, -vs- LORILLARD TOBACCO COMPANY, INC., LORILLARD, INC., LOEWS CORPORATION COUNCIL FOR TOBACCO RESEARCH-USA, INC.,(Successor to Tobacco Industry Research Committee), AND TOBACCO INSTITUTE, INC., Defendants.	)	Index No 110949/96

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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

MARY ANN HOSKINS, Executrix of the Estate of Edwin Paul Hoskins, WALTINA BROWN and DANTE AUBAIN, individually, and on behalf of others similarly situated,	)	
Plaintiffs,	)	
-vs-	)	INDEX No 110951/96
R.J. REYNOLDS TOBACCO COMPANY, RJR NABISCO, INC., COUNCIL FOR TOBACCO RESEARCH-USA, INC., (Successor to Tobacco Industry Research Committee), AND TOBACCO INSTITUTE, INC.,	)	
Defendants.	)	

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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

SHARLENE HOBERMAN and AUDREY HULSE, as executrix on behalf of the Estate of Lewis Hulse, individually, and on behalf of others similarly situated,	)	
Plaintiffs,	)	
-vs-	)	Index No 110953/96
BROWN & WILLIAMSON TOBACCO CORPORATION, B.A.T. INDUSTRIES P.L.C., BATUS, INC., BATUS HOLDINGS, INC. COUNCIL FOR TOBACCO RESEARCH-USA, INC., (Successor to Tobacco Industry Research	)	

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Committee), and TOBACCO INSTITUTE, INC.,

Defendants.

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

ROSE FROSINA, ELIZABETH COLAVITO and ANILDA ROSS, individually, and on behalf of others similarly situated,

Plaintiffs,

-vs-

PHILIP MORRIS, INC., PHILIP MORRIS COMPANIES, INC., COUNSEL FOR TOBACCO RESEARCH-USA, INC., (Successor to Tobacco Industry Research Committee), AND TOBACCO INSTITUTE, INC.,

Defendants.

INDEX No 110950/96

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

CATHERINE ZITO, PETER HOBERMAN, and GEORGE ELISSEOU, individually, and on behalf of others similarly situated

Plaintiffs,

-vs-

THE AMERICAN TOBACCO COMPANY, INC., AMERICAN BRANDS, INC., COUNCIL FOR TOBACCO RESEARCH-USA, INC.

INDEX No 110952/96

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(Successor to Tobacco Industry Research Committee), AND TOBACCO INSTITUTE, INC.,

Defendants.

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DEPOSITION OF DR. C. ROBERT CLONINGER
TAKEN ON BEHALF OF THE PLAINTIFFS

NOVEMBER 13th, 1997

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DEPOSITION OF DR. C. ROBERT CLONINGER,

taken to be used in actions pending in the United States District Court, Eastern Division, Northern District of Ohio, State of Ohio, and in the Supreme Court of the State of New York, County of New York, pursuant to agreement between counsel, under the provisions of Rule 26(a) of the Rules of Civil Procedure, taken on the 13th day of November, 1997, between the hours of eight o'clock in the forenoon and six o'clock in the afternoon of that day in the offices of St. Louis Marriott, Airport, I-70 at Lambert International Airport, St. Louis, MO, in certain causes now pending in the United States District Court, Northern District of Ohio, Eastern Division, and The Supreme Court of the State of New York, County of New York; on behalf of Plaintiffs.

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A P P E A R A N C E S

FOR THE PLAINTIFFS, Hoskins/Chamberlain

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By: Dennis Murphy, Esquire

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DR. C. ROBERT CLONINGER,

of lawful age, being first duly sworn to tell the truth, the whole truth, and nothing but the truth, deposes and says on behalf of the Plaintiffs.

DIRECT EXAMINATION

BY MR. MAISTROS:

Q. Could you please state your full name for the record?

A. Claude Robert Cloninger C-L-O-N-I-N-G-E-R.

Q. And is it Dr. Cloninger?

A. That's correct.

Q. My name is Jack Maistros. I'm going to be asking you a series of questions in two matters. One of which is Judith Chamberlain, et al., versus American Tobacco Company in the Northern District of Ohio, Eastern Division, Case Number 1:96CV2005; are you familiar with that case?

A. Yes, sir.

Q. And the other case is Hoskins versus R.J. Reynolds Tobacco Company -- Hoskins et al., actually, versus R.J. Reynolds Tobacco Company et al., in the New York County Court, Case Number 110951/96; are you familiar with that case?

A. Yes, sir.

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MR. MAISTROS: And as I understand it, you're here today just on those two cases, counsel; correct?

MR. NIMS: That's my understanding as well.

Q. (By Mr. Maistros) If at any time, Dr. Cloninger, you don't understand my question and you want me to rephrase it, ask me; okay?

A. Okay.

Q. If you want to take a break, let me know. If you want a glass of water, let me know.

A. Okay.

Q. If at any time I use a phrase and you think I'm using it improperly, tell me.

A. Okay.

Q. If I use a word that you believe has different meanings, I'd like you to tell me as well. So there's no confusion on the record what I'm asking you; do you understand?

A. Yes.

Q. Okay. Now, have you seen the notices of deposition in both of the cases I've cited?

A. I discussed the one with Chamberlain with Mr. Nims yesterday, but I have not seen the one in Hoskins.

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Q. If you would take a moment to look at Plaintiffs' Exhibits Number 1 and Number 2, those are the notices of depositions. Plaintiffs' Notice 1, being in the Chamberlain case, and Exhibit 2 being in the Hoskins case, and ask you if you have seen the document requests that went along with those notices?

A. The answer is yes to Chamberlain and no to Hoskins.

Q. Okay. Let's go through first Hoskins if you might, Exhibit 2. Notwithstanding the fact you have not seen the Hoskins notice or the document request, you have brought documents in Hoskins?

A. Yes, sir.

Q. And we'll go through those in a moment, but if you look at the list of requested documents in Hoskins, among the documents requested is number one, your most current CV; has that been brought?

A. I furnished that. I didn't bring a copy myself, but I believe you have it.

Q. Is the one I have dated March of '97 your most recent?

A. Yes.

Q. And have you brought a full copy of your expert report?

A. Yes.

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Q. Have you brought drafts of your report?
A. There were no drafts.
Q. Maybe we can do this together for both of these cases. Have you brought a full copy of your expert report in Chamberlain?
A. Yes.
Q. And were there drafts of that report?
A. No.
Q. When you say there's no reports, do you mean the first time you drafted both the Hoskins and Chamberlain's report that was a final version that was submitted?
A. Yes.
Q. It wasn't based upon any reports in any other cases?
A. Parts of it were taken from other depositions, but in each case, it was modified to be appropriate for the specific report but sections of other depositions that I've given that cover the same material are sometimes used.
Q. Sections of other depositions or sections of other reports?
A. I'm sorry, reports.
Q. If you -- when we get to both the Hoskins and Chamberlain report, would you be able to identify

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which portions were original to these cases and which were taken from other reports?

A. I believe I could.

Q. Okay. And number four category, all documents, writings, other tangible items, you've prepared, received, reviewed, in preparing your report, and then it goes on to list some items; do you see those?

A. Yes.

Q. Have you brought all such documents?

A. Yes, I brought my full file.

Q. And number five, have you brought those items, all documents, writings, textbooks, treatises, etcetera, that you've reviewed and relied upon in connection with your reports?

A. Well, in the course of my career, I have read and assimilated information from a large number of articles and textbooks and other sources of information. It's not practical to carry that around. I don't think I could, in fact. But, in fact, my opinions are based on my accumulative expertise as reflected in my curriculum vitae.

Q. Are there any particular writings or documents that you relied upon in the course of preparing your report that you could identify for

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me --

A. Anything that was specific to this report actually referred to in the report, for example, articles by Dr. Fiore, that I cited in my report in Hoskins, I brought a copy of that with me. Anything unique to this case, I brought with me.

Q. Okay. For example, if you cite to the '88 surgeon general's report, have you brought that?

A. No, I didn't.

MR. MURPHY: Jack, let me just state that we had some correspondence about the surgeon general's reports, and we know that you guys have those and that was the subject of some of the correspondence.

Q. (By Mr. Maistros) Number six, all documents prepared or generated by the deponent in connection with your report including correspondence; have you brought such documents?

A. I brought everything --

Q. I'm paraphrasing by the way. So the record is clear, the items on schedule A to the New York notice; okay?

A. Okay.

Q. You've brought everything for number six?

A. Yes, sir.

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Q. Now, number seven is all documents, writings, materials, or other tangible items related to or arising from any research or other scientific endeavor conducted by you and then it goes on, which forms the basis of or supports your opinions; have you brought such documents?

Specifically, I think the focus of this request is if you've done any actual research related to opinions you've offered in your reports as opposed to literature review?

A. I'm not sure I really appreciate what is really meant by the scope of this because it is so general that it conclude -- it could include everything.

For example, I've done hundreds of studies over my career on which I use information in formulating my opinions, and I certainly have not brought copies of original interviews or statistical data tapes or other things that are reflected in my published papers. I haven't brought that kind of documentary evidence, but I do have such information. It's available if it is specifically necessary.

Q. Okay. Well, we'll deal with it as we go through the reports. In number eight is documents showing what you've billed for consulting fees

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related to these matters?

A. Yes.

Q. You've brought those?

A. I've brought a list of my time on these cases. I haven't -- I don't believe I've actually billed in these cases yet.

Q. Number nine is all correspondence or documents reflecting communications with anyone regarding any issue related to these cases; have you brought such documents?

A. Yes.

Q. And number 10, all articles, reports and/or papers published or unpublished that were prepared by or at your direction which forms the basis or supports the opinions in your reports and then lists a whole bunch of categories; have you brought such documents?

A. I'm surprised at the scope of this request because as I read it, it could be construed to imply that I should bring all drafts of all articles that I've ever written in my life, and I have a rather lengthy CV with over 200 publications and several books and, of course, I did not bring such material with me. But you have a copy of my curriculum vitae and if there's something of specific relevance to

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this case, I'd be happy to discuss with you what you need in the way of documentation if it should be necessary.

Q. But you have not brought any documents responsive to number 10?

A. I brought all material relevant to this case specifically and my curriculum vitae, which lists my scholarly activities. I would hope that that would be sufficient to allow you to make any more specific requests that you would need because 10 is beyond the scope of reasonable effort.

Q. You didn't see 10, though, before?

A. No, I didn't.

Q. I just handed it to you; did you?

A. No.

Q. Number 11, did you bring videotapes or transcripts of your prior deposition or trial testimony?

A. I don't have those.

MR. MURPHY: And let me state that those were furnished to your office some time ago in an effort to dispense with the need to depose Dr. Cloninger, at least in the Chamberlain case, and you declined that offer.

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MR. MAISTROS: I didn't decline the offer to receive the deposition.

MR. MURPHY: No, you declined the offer to dispense with the deposition in the Chamberlain claim.

Q. (By Mr. Maistros) Okay. Now, mark as Exhibit 3 a copy of your CV that I was provided.

(A certain document was marked Exhibit Number 3 for identification by the Reporter.)

MR. MAISTROS: I'm sorry I only brought one extra. It's so big.

Q. (By Mr. Maistros) Is Exhibit 3 the most current version of your CV?

A. I believe so.

Q. And did you prepare this CV?

A. Yes.

Q. Were there any articles that you've authored that are not on this CV?

A. Let's see, since March I have written some papers but none of those are specifically relevant to this case. All those that are relevant are listed.

Q. Have you written any papers on nicotine?

A. Well, if by nicotine you would include cigarette smoking.

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Q. No, just nicotine.

A. Not specifically on nicotine.

Q. Since March?

A. No.

Q. Have you written any papers on cigarette smoking since March?

A. No.

Q. Have you reviewed any books since March that aren't on this list?

A. No.

Q. Have you been an editor on any publications since March that are not on this list?

A. Well, as an editor I don't list the papers that I review for publication, but I have not become an editor of any additional journals since March.

Q. Have you been appointed to any professional societies or organizations or joined any professional societies or organizations since March that are not on this list?

A. I have been a consultant to the National Institute of Health for Drug Abuse and for Alcoholism since March in connection with the reviews of the epidemiology and genetics of drug abuse and alcoholism. That was just in September and October, actually September and November of this year.

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Q. And by a consultant you mean you're being paid, or?

A. I was an invited paid consultant to NIDA and to NIAAA for view of research programs that they are considering initiating on substance abuse and alcoholism.

Q. Genetically related or just substance abuse and alcoholism?

A. They are related to the genetics of substance abuse and alcoholism.

Q. And when you say you were being paid, is it you or your employer?

A. In the case of consultant consultation to the NIAAA those fees do go directly to me.

Q. What is NIAAA?

A. That's alcoholism and alcohol abuse.

Q. Is that a subcommittee of the National Institute of Health?

A. Yes -- well, it's one of the institutes in NIH. And NIDA N-I-D-A is also one of the institutes of NIH.

Q. And this subcommittee is exploring the possibility of research related to substance abuse insofar as genetics is concerned?

A. That's correct. The fees are very minimal.

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Mainly they pay your expenses and I think $200 or $300 a day.

Q. Have you received any further education or academic degrees since March of '97 that are not on this CV?

A. Other than attending scientific meetings, which I receive continuing education -- continuing medical education credit, no.

Q. Have you received any university appointments of positions since March of '97 that are not on this CV?

A. No.

Q. How about hospital appointments?

A. I was appointed to the medical advisory committee of Barnes -- Barnes Jewish Children's Hospital for evaluation of complimentary medicine practices.

Q. What are complimentary medicine practices?

A. Things like yoga and acupuncture, alternative medicine techniques that are becoming increasingly popular in the United States and elsewhere. They require expert medical evaluation as to their efficacy and safety before they can be provided under hospital auspices.

Q. Is hypnosis included in there?

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A. Yes. Herbal medicine and so on.
Q. Now, your current employer is who?
A. Washington University.
Q. And that's located here in St. Louis?
A. Yes.
Q. And how long have you been employed there?
A. Since 1970.
Q. Do you have any other employers?
A. No.
Q. Do you have a private practice?
A. As part of my activities at Washington University.
Q. And where is your office?
A. Renard Hospital, which is a part of the Barnes Medical Center Complex.
Q. So you receive compensation from Washington University?
A. That's correct.
Q. And you receive compensation from your private practice?
A. Well, private practice actually is a part of my activities, so those fees -- most of those fees actually for clinical care of patients go directly to the university. We are allowed to do some consultation service on advisory committees and

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receive honorarium and fees for consultation and to industry and for lectures and writing royalties and so on.

Q. But if I wanted to come see you for counseling I would pay or send my check to Washington University?

A. That's correct.

Q. If I have health insurance coverage, who in your office fills out my health claim forms?

A. We actually have a division now that does that, but it is -- these are employees of the Department of Psychiatry that do it.

Q. How do the employees know -- for example, if I come in for a consultation, how do the employees know what to put down on the health insurance claim?

A. Well, I have forms that I fill in that then give them the essential information. They actually prepare the forms from the forms that I fill for them that list various codes and procedures that I carry out.

Q. Now, what codes do you use?

A. I actually couldn't tell you the exact numbers of the codes, but we have -- that's why we have a form because most people don't actually remember the code numbers themselves.

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Q. What have those codes -- have you developed those codes on your own?

A. No, those are standard fee for service codes that are generally regulated by the Medicare and other insurance providers.

Q. Do you know what those codes are called?

A. What is it? Oh, what is it? I want to say CPC, but I can't -- it's clinical practice code and then there are certain numbers that go with that. I'm not sure I have all the initials exactly right, but it's CP something.

Q. Now these codes, do they correspond to treatment or?

A. Yes.

Q. What do they do -- I mean --

A. Well, they would be things like one-hour consultation outpatient, inpatient diagnostic evaluation, personality assessment, pharmacological management.

Q. Is there a code for prescribing medication?

A. Yes -- well, that would come under pharmacological management.

Q. Pharmacological management?

A. Yes.

Q. Do you know what the term "medical

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necessity" means?

A. Medical necessity?

Q. Yes.

A. I know what those words mean. If it has a technical legal meaning, I'm not sure.

Q. How about "medically necessary"?

A. Same. I'm not sure what -- if you're raising an issue of some particular statute or practice.

Q. Do you have contracts with any insurance companies whereby you agree to treat certain patients and then bill the insurance company for those services?

A. I don't personally but our department does, and I'm listed as provider on a number of contracts that the department as a whole has.

Q. You actually have a provider number?

A. I may. I suppose I do or they couldn't keep track of it, but I don't actually pay much attention to that. I leave that up to the department, and I regulate the amount of time that I see in clinical practice.

Q. Do you actually --

A. I --

Q. I'm sorry; are you done?

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A. Yeah, I'm done.

Q. Do you actually sign the insurance claim forms when they're submitted to the insurance companies?

A. I sign a form that is kept on record by our business office in which I communicate to them what services I'm providing. I don't fill -- I don't sign the forms that they then provide from that.

Q. Do you know if there's any requirement when you submit an invoice or a request for payment to the insurance company that the services you provided were medically necessary?

A. Medically necessary? Well, our -- we've recently instituted an audit procedure whereby every billable activity is actually then documented by a written note that is reviewed in the business office to assure that the services provided correspond to the code. And we do also in the case of hospitalization and outpatient activities generally require or are generally required to obtain pre-certification by the insurance agency or the insurance provider as to whether they will allow the service. We have to convince the certifying agent that the service that we're requesting to provide is necessary for the patient and then they give us an

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authorization for carrying out that activity.

I may still, if they don't authorize it or if the patient has exceeded the benefits of their contract with the insurance provider, I may still, in my opinion, feel that the patient needs the service in order for me to maintain adequate standards of care for my -- according to my judgment. And in that case, I then go ahead and I provide the service at no charge to the patient or I make some arrangement for them to provide directly if that's allowable.

Q. Before proceeding with any recommended treatment or prescriptions, do you make it a practice of yours to make certain that those treatments or prescriptions are medically necessary?

A. I would not provide a service that I didn't think was indicated. In other words, if I didn't think it would be of benefit to the patient. However, there are many things that can be beneficial which are not necessary for survival or for comfort. And so, again, I would have to know what is the standard for necessary.

What I usually operate by is what's good for the patient and the sense of what's necessary may have some other meaning to other people

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or in connection with some statutes I'm not aware of.

Q. You are -- you provide services that are compensated by Medicaid?

A. Yes.

Q. And Medicare?

A. Yes.

Q. And private insurance companies?

A. Yes.

Q. And through the State? Is there a distinction or is your Medicaid, Medicare handled through the State here?

A. Well, it has been both ways. In the past it was done directly by the State, and I have worked in the State Mental Health System in the past, I don't currently, but now at this time the services for the State are actually farmed out to private contractors and insurance providers.

Q. Have you treated people for what they claim to be smoking addiction, habituation, dependence?

A. Yes.

Q. Without getting into what those three words mean --

A. Yes.

Q. -- what's your general course of treatment for such people?

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A. Well, it depends on each individual case. There's no set procedure that I would follow in all cases. It really would depend on the particular individual's diagnosis, history, and feelings about personality, feelings about other goals and activities that they want to engage in.

Q. Is it part of your practice to attempt to determine if somebody is addicted, dependent, habituated to tobacco without such patient first raising the issue with you?

A. In doing an initial and ongoing examination of the psychiatric history, I consistently ask about use of all substances, including cigarettes.

Q. Do you ask your patients how much they smoke?

A. Yes.

Q. Do you ask them how long they smoked?

A. That would be part of my evaluation.

Q. Do you ask them if they have tried to quit smoking?

A. Generally, yes.

Q. Do you ask them how many times they've tried to quit smoking?

A. In answering these questions about what I would ask about, I would just say that that will vary

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from patient to patient, depending on the overall context.

For example, if someone is a poly substance abuser and I may not go into as much detail about quantity and frequency and duration of the cigarettes. It would depend on what is the relative prominence of that behavior in their overall picture.

So generally I would want to know what the pattern of their behavior is and what its significance is in their life and just what details I need to know about that in order to evaluate that would vary from case to case. So again, there's not a ritual where I ask a fixed set of questions of every patient in every case.

Q. Let's take the patient who comes in who is not on heroin, is not on cocaine, is just coming to see you because they're not satisfied with their life in general, say take a mildly depressed person. Would you get into issues of whether or not they smoked?

A. Yes.

Q. What type of questions would you ask them?

A. Well, I would want to know how much they're smoking, when -- in terms of current use and then from there I would proceed to what the -- when they

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Source: https://www.industrydocuments.ucsf.edu/docs/vjxl0001

started, whether they've stopped, whether they've -- what sort of symptoms they've had, what pleasures they've derived from it.

Q. Is that while they're smoking or when they stopped?

A. I would want to know both their behavior before, during, and after any smoking behavior.

Q. Have you had patients describe to you symptoms, unpleasant symptoms, they've experienced when they've attempted to stop smoking?

A. I have had that.

Q. Have patients actually used phrases, such as "I go through withdrawal symptoms when I've tried to quit smoking"?

A. Yes, in some cases.

Q. Now, when you fill out your insurance claim forms is there a category that you put down for diagnosing somebody that's nicotine dependent, habituated, addicted?

A. We do have a -- we do use the official codes for psychiatric diagnosis and substance dependence is one of those codes.

Q. What do you mean "the official codes"?

A. The American Psychiatric Association has a diagnostic and statistical manual that conforms to

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the criteria of the international classification of diseases that has a list of specific codes that include nicotine dependence.

Q. Are those what is referred to as the DSM's?

A. Yes.

Q. And the current one is DSM-IV?

A. Correct.

Q. Roman Numeral four?

A. Correct.

Q. So when a patient comes to see you and you diagnose him for, what is it called in the code, nicotine dependence?

A. Yes.

Q. Is there's actually a code number you put down that, say, you did the diagnostic procedure outlined in the code?

A. Yes.

Q. What makes that code official?

A. The standard of practice requires the use of codes based on the International Classification of Diseases.

The United States has a treaty or an agreement with the World Health Organization to do that, and it's been elected for psychiatric diagnoses in the United States that we use a modification of

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the ICD criteria developed by the American Psychiatric Association, the DSM. Those are considered official guidelines to clinicians. In fact, those are guidelines and so you don't always know if someone uses that code, exactly what questions were asked or what the evidence is or what its quality is.

So there are -- there are questions about the validity of the diagnostic criteria, so it's -- it is a label that has some merit, but there are limitations to it from a standpoint of validity or what its meaning is actually.

Q. Well, my original question is, what makes it official, and you originally started out with it was an offshoot of the World Health Organization Treaty?

A. Yes.

Q. And is it your testimony that licensed psychiatrists, such as yourself, must put down a diagnosis under DSM-IV?

A. Well, again, you used the word "official" and you asked me to --

Q. Well, you --

A. -- call to your attention if you used a word that could be ambiguous or could have multiple

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meaning, and my reply to you was that in one sense it's official because it's a part of this agreement, and we always have to use these codes in order to communicate what we're doing providing service for. We don't always communicate all codes that could be applied to a patient if we're not providing service about that diagnosis.

For example, I often see patients who have heart disease or who might have minor behavior problems, and I don't necessarily record all of their codes. I generally require -- I do list the codes that are their primary diagnoses or those for which I am providing direct service.

Now, the other part of my clarification of your question to me is that I think the word "official" could also be used to imply that it is something that is valid and somehow certified as a valid diagnosis by some group or person, and I don't think that -- I think there are questions about the validity of some of the diagnostic criteria that we use in ICD-X or DSM-IV, and so depends on what you mean by official.

Q. Well, you used the word not me.

A. No, sir, you did.

Q. That was back --

Source: https://www.industrydocuments.ucsf.edu/docs/fdxl0001

A. You asked me a question about official.

Q. But that was in response to you identifying the DSM-IV as the official codes of psychiatric diagnosis. That's why I asked you originally what did you mean by official.

A. Oh, I see.

Q. That takes us back to my original question.

MR. MURPHY: I'm going to object that you're misstating his former testimony.

MR. MAISTROS: It is what it is but --

MR. NIMS: And in any event, he's clarified the various meanings that official might have in his view.

MR. MAISTROS: Is that what you've done?

THE WITNESS: Yes, sir, tried to.

Q. (By Mr. Maistros) So if I understand it, when you diagnose somebody as nicotine dependent, you don't have to use DSM-IV?

A. DSM-IV provides criteria that can guide a clinician, but I don't believe that everyone who uses those diagnoses actually always asks all the diagnostic criteria that are recommended --

Q. I'm just asking about you.

A. -- for these. I'm sorry?

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Q. I'm just asking about you.

A. When I use that diagnosis, it would be because I believe that I've reviewed the criteria and that they're satisfied.

Q. Now, when you submit claim forms to either Medicaid or private insurance companies, do you certify that you've diagnosed people as nicotine dependent under DSM-IV?

A. I don't believe I can remember, at least in the last decade, any time when I have recorded a diagnosis of nicotine dependence on a claim form because generally I have not found that to be a primary diagnosis in patients that I'm treating. Even though that doesn't mean that I haven't recognized that they smoke cigarettes, but I do not remember a single case in which I put that on an insurance claim form because that was never what I was primarily treating the patient for.

Q. Is there a DSM-IV classification for heroin dependence?

A. Yes.

Q. And have you diagnosed people as being heroin dependent?

A. I have.

Q. And have you submitted to insurance

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companies or Medicaid claim forms diagnosing somebody as heroin dependent?

A. Yes.

Q. And have you used DSM-IV or III?

A. III or IV, both.

Q. Have you used any other quote "official" unquote diagnostic specification for such diseases or disorders?

A. If I understand the question, I've always used DSM-III and IV.

Q. Okay. And that's regardless of if it's nicotine dependence, heroin dependence, cocaine dependence?

A. Correct.

Q. Or depression?

A. Correct.

Q. Is there any other similar official set of standards you rely upon in your practice?

A. Rely upon?

Q. I'm talking about for if, you know, DSM-IV if you could characterize it as an outline of tools to diagnose various disorders; correct?

A. Yes.

Q. Are there any other similar publications put out by any other entity that you rely upon?

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A. Again, I'm not sure what you mean by "rely upon." Could you be more specific?

Q. Sure. There's two issues, are there not, with DSM-IV. It provides you a guideline for diagnosing somebody if they have a disorder; correct?

A. Yes.

Q. And it also provides you a specification to bill a third party, such as Medicaid or private insurance companies, once you've arrived at a diagnosis; correct?

A. Yes.

Q. Either when you're diagnosing or when you're billing, do you rely upon any other type of specification similar to DSM-III, IV, etcetera?

A. For billing I always use the DSM system. For diagnosis and evaluation, describing the patient, I take into account a number of other approaches to diagnosis and classification. The International Classification of Diseases, which is currently in its tenth edition, corresponds in terms of codes and labels to DSM, but it actually uses different criteria. So that different criteria are actually used by different people in different countries but they arrive at the same diagnosis.

I'm familiar with the ICD-10 and its

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predecessors and I sometimes use that and use those, in fact, when I characterize those differences in order to better and more fully describe the patient. There are other systems, for example, with regard to nicotine tobacco use that I'm familiar with and I may use and might rely on for certain kinds of descriptions or diagnoses but not for billing. Those would include things like the Fagerstrom criteria for dependence in the case of substance use and a variety of other diagnostic systems for other aspects of psychopathology.

Q. When you bill either your patients, third parties, governmental entities, you use the DSM's?

A. Yes.

Q. And how long have you been doing that?

A. I've always done that.

Q. Have you ever prescribed any nicotine substitute to any of your patients?

A. Yes.

Q. Which ones.

A. I have occasionally prescribed patches and gum. I don't remember exactly what brands. It's not something that I do very frequently because I don't think it's generally necessary.

Q. Is there a DSM for patches or gum?

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A. There's not a -- there's not a code for those, no.

Q. For Medicaid do they have a code that you have to use when you prescribe patches or gum?

A. No.

Q. Do private insurance companies have a code?

A. No.

Q. Do you have an internal standard, such as -- well, start over.

You're a medical doctor; correct?

A. Yes.

Q. What standards do you have to meet before you can prescribe medication? What do you have to find?

A. Again, the general rule would be that you would want to use a medication that would be of benefit to the patient and outweigh the risks involved in prescribing it and that's always a risk benefit judgment based on the diagnosis of the patient and what their requests are and various aspects of information about the efficacy and side effects of the drug.

Q. Can you describe a medication without making a finding that such medication is medically necessary to that patient?

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A. Yes. If you mean by "necessary" that it would be requisite for survival or comfort, it may be something that you could use to enhance the way they feel or to reinforce their motivation or to give them something tangible to encourage them to do what they want to do.

Q. Do you have to find that the patient would achieve a medical benefit before you prescribe a certain medication?

A. You would not prescribe -- I would not prescribe something that I did not think would be where the benefit would not outweigh the risks. Of course, that's always a judgment and estimate that you make.

Q. If I came into your office and said I believe I'm dependent upon cigarettes, would that be enough for you to prescribe me the patch or gum?

A. No.

Q. What else would you need?

A. Well, I'd need to know what the full situation was and I'd have to -- I would do a complete psychiatric review, try to understand the current situation. I also would, in the case of nicotine, would probably tell you that I didn't think that it was necessary for you to use this, that the

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symptoms of withdrawal that are described are mild and transient and actually don't occur in most people and so that it's not necessary in most cases.

However, if in further discussion with you it appeared to me that the use of something like this would be of symbolic value to you or would encourage you or remind you that you were doing something of benefit for you, I might still go ahead and use it even though I didn't think it was necessary if I thought it would be an effective motivational tool to accomplish the goal.

Q. Is it your opinion that patches and gum only have symbolic value to people that are nicotine dependent?

A. I think they have limited and transient value and that they do not -- their use does not have a substantial effect on the ability to stop smoking in most cases.

Q. What studies have you done on patches?

A. I've reviewed the literature.

Q. Which literature?

A. Literature about the use of patches.

Q. Which literature?

A. Overall reviews of the efficacy. I believe if you look at essentially any review, that you will

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find that nicotine levels or use of nicotine replacement therapy do not predict the success.

Q. I'm just asking what literature you've reviewed.

A. And I'm telling you.

Q. No, you're telling me what the literature says. I'm asking what literature you've reviewed.

A. One specific book that does a summary of this is a book on nicotine addiction called "Nicotine Addiction" by Orleans and Slade. I've also reviewed and cited an article by Dr. Fiore, Fiore one of the experts in Hoskins, that also makes reference to studies of nicotine replacement therapy. All of these sources show that the primary predictors of success and smoking cessation primarily have to do with self-directed determination to stop and not with nicotine levels or nicotine replacement efforts.

Q. Okay, we'll get into whether or not you believe in the merits of nicotine replacement later this afternoon. I'm just interested in what literature you've reviewed. You cited this Orleans, Slade publication?

A. Right.

Q. And the Fiore article?

A. Right.

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Q. What was the Fiore article entitled?

A. It's included here in my folder.

Q. Okay.

A. "Predicting Smoking Cessation: Who Will Quit With and Without the Nicotine Patch." First author, Susan L. Kenford, and then there are several others including second author, Michael Fiore. That's in JAMA, Volume 271, pages 259 to 294, and the year is 1994.

Q. When did you read that article?

A. I read that shortly before I prepared my report, which was --

Q. I think it's October.

A. I prepared it -- I read it the week before October the 13th, so in October of '97.

Q. And when did you read the Orleans, Slade book on nicotine addiction?

A. Let's see, I think that's about a 1994 publication, maybe a '93 publication, but I would have read it approximately 1993 to '94.

Q. Now, the Fiore article, how did you come to find that article?

A. I looked at the curriculum vitae of Dr. Fiore, which was provided in this case, and I looked to identify any articles that he had written

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that had to do with smoking cessation and then I went to the library and obtained it.

Q. So you read Dr. Fiore's article on predicting smoking cessation in preparation for your report in this litigation?

A. Correct. I wanted to see what his opinion was and what articles he had written.

Q. Have you written any articles on smoking cessation?

A. Yes.

Q. Which ones?

A. One article is entitled "Epidemiology and Axis I Comorbidity of Antisocial Personality" disorder. It's listed in my CV as article 231.

MR. MAISTROS: We'll mark this as Exhibit 4. You know what? Is there any objection to marking these?

THE WITNESS: No.

MR. MAISTROS: We'll give you the -- I'll try to identify them as we go along, if we can return the originals to the witness and just keep copies. Four will be one of those.

THE WITNESS: That's fine.

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Source: https://www.industrydocuments.ucsf.edu/docs/vtxl0001

(A certain document was marked Exhibit Number 4 for identification by the Reporter.)

Q. (By Mr. Maistros) Now Exhibit 4, Epidemiology and Axis I Comorbidity of Antisocial Personality, this is on smoking cessation?

A. There's a section that deals with smoking. It's the last two paragraphs in substance abuse.

Q. When did you author this article?

A. I wrote it in '96 and it was published in '97, earlier this year. Actually, I think I wrote it in '95. Yes, I did.

Q. Is this the only article you've written or the only article you've written that touches upon smoking cessation?

A. Well, there's another section on cigarette smoking in a book about temperament and character inventory that I've authored that gives similar kinds of association findings. Basically, this is -- the two have similar content. Although, one is a review of other literature, work done by others.

Q. Where is that on your CV? Is that 222 by any chance or 223?

A. It's actually a book. I'll be darned. I forgot to list a book I wrote. The title of the

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Source: https://www.industrydocuments.ucsf.edu/docs/ylxl0001

book -- I apologize. Actually, I had never noticed that I had forgotten to list one of my books. The title is the "Temperament and Character Inventory: A Guide to Its Development and Use." First author is C.R. Cloninger. Second author is T. Przybeck P-R-Z-Y-B-E-C-K. The other author is D.M. Svrakic S-V-R-A-K-I-C, and fourth and last author is R. Wetzel W-E-T-Z-E-L. That book is a manual for the personality test, the TCI, that I developed and it's published by Washington University in 1994.

Q. Is that a personality test?

A. Yes.

Q. And how long is that book?

A. It's 185 pages. The section on cigarette smoking is only about -- I think about four pages, something like that, four or five pages.

Q. Do those four or five pages focus upon cigarette smoking in terms of personality traits?

A. Yes. The whole issue is the association between personality and smoking, not about smoking cessation directly except having to do with differences between people who can be described as dependent or not.

Q. Okay. Has any of your writings -- have any of your writings focused upon the issue of smoking or

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nicotine dependence in terms of nicotine?

A. No.

Q. Have --

A. I've done some genetic work on nicotine receptors in connection with some of my graduate students, but nothing that I think is really relevant to nicotine as a pharmacological agent.

Q. Now, when did you first do work on nicotine receptors with your graduate students?

A. Oh, let's see, about 1990.

Q. What was the goal or purpose of that work?

A. This was dissertation on molecular genetics of nicotine receptors and their evolution from primates to humans.

Q. Was any of that work published?

A. Yes.

Q. Where?

A. The first author, the principle author, is Betty Lobos L-O-B-O-S. I may have been a co-author with her on some things. I don't -- I don't think I was actually but.

Q. Is that in your CV?

A. Well, if there is a publication, it would be in my CV, but I don't believe I was a co-author with her. That would be been published independently

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by her.

Q. Is she a graduate student?

A. Yes, at the time. It is a purely basic science study not a clinical study.

Q. What's the difference between a science study and a clinical study?

A. In other words, it had to do only with molecular genetics and molecular biology and not with human behavior.

Q. Now, if we can go back to your practice, we'll call it a practice. I guess we better figure out what percentage is actually a practice versus teaching versus whatever. Can you tell me what you do on a typical day in St. Louis?

A. That would vary so much that it would be easier to tell you percentages overall in the year.

Q. Why don't you do that?

A. Approximately 20 percent of my time is in outpatient care -- or is in patient care and that includes both inpatients and outpatients. And that probably is an adequate answer.

Q. And typically what us lay people think is doctor-patient stuff?

A. Yes.

Q. Diagnosis, treatment, run around the

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hospital?

A. Right.

Q. Okay. That's 20 percent.

A. Oh, you want my full percentage of times?

Q. I'm not looking for your --

A. Another --

Q. I'm not looking for your leisure activities. This is just what you do --

A. I understand. 20 percent in patient care; about 15 percent in teaching involving patient care, supervising other doctors and training in their patient care; and another 10 percent in lecturing and teaching; another 55 percent would be in direct research.

Q. And for how many years has that been the general breakdown?

A. Probably 10 years.

Q. And how much of your 20 percent time that you spend in patient care is related to substance abuse?

A. I don't directly -- I don't -- I don't subdivide my patient activities into that concern with substance abuse or not but --

Q. Maybe abuse --

A. But percentage of patients.

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Q. Is abuse the wrong term? How about substance dependent?

A. Well, the percentage of my patients that do have substance abuse or dependence as a diagnosis would be probably -- let's see, I'm trying to think of a good basis for giving you an estimate. That's probably about a third of my patients would have some form of substance abuse.

Q. What are the rest? Just depression, mental disorders?

A. Yes. And most of those with substance abuse would also have other mental problems.

Q. And how many of those one-third substance abuse patients have you diagnosed as being nicotine dependent?

A. Small percentage. I can't give you an exact number. I actually don't think that the diagnosis of nicotine dependence has a lot of validity or use or applicability in practice. I generally find it adequate to simply focus in on the pattern of behavior of the patient, and I don't find that label particularly helpful.

Q. And why is that?

A. It just doesn't have much validity to support it in terms of the research that's been done.

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It's trying to force -- the whole approach in DSM has been to try to force all patterns of use of any substance into a common framework of dependence.

The dependence concept actually derives from alcoholism research and it's only subsequently been related to other drugs and fitting cigarette use into that model of substance dependence as was developed on the basis of other drugs, like alcohol and heroin and cocaine, is really trying to fit a square peg into a round hole.

Q. Now, are you familiar with a general school of thought out there that in terms of drugs of dependence, such as heroin, cocaine, some people believe the pharmacological effect is more important than personality and vice versa?

A. Well, you would have to be a little more specific about what you're saying because --

Q. Okay. Let me break it down then. Are you familiar with a school of thought that one should look to, first and foremost, personality characteristics of a drug-dependent person as opposed to the actual pharmacological effects of the drug in diagnosing such a person?

A. Well, you're putting it in a way that doesn't really sound very familiar to me.

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Q. Let's take alcohol. You've done some work in alcohol; haven't you?

A. Yes.

Q. How would you characterize your general -- if you had to sum up your general belief as to why certain people become alcoholics, why don't you tell me what it would be?

A. Well, that's a very active and complicated and controversial research area right now.

Q. Just your belief.

A. Actually, that statement still would bear on my understanding of it, where I'm actively engaged in a number of research projects in which the fundamental question even with alcohol, which is probably the best characterized of all drugs of abuse and dependence, they're active questions about how to define dependence, who's dependent, and then there are active questions about the etiology and the relative contributions of genetic factors.

That's fairly settled that it's highly heritable but what is the nature of the genetic predisposition? Is it for individual differences in response to alcohol metabolically? Is it individual differences in personality traits? Is it individual differences in brain responses to a variety of other

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kinds of emotional stimuli? These are very active areas of investigation. I'll try to answer your question, though, but I want you to understand that these are not settled issues.

Q. I'm just looking for your view.

A. My view is that alcohol use, abuse, and dependence is a complex interply of genetic predisposition to certain personality traits that influence the initiation and continuation and stopping of alcohol abuse, and that there are other non-personality related genetic and biological factors that interact with those to create differences between people and their susceptibility to alcoholism.

Q. Do you give any weight to the pharmacological effects alcohol has on the human system?

A. Yes, there are replicated differences in the way people respond to alcohol initially in terms of the degree to which they become intoxicated by it, that are predictive of their susceptibility to alcoholism. There are differences between ethnic groups in the way they metabolize alcohol, such as whether you flush or not, that are predictive of whether you're likely to become alcoholic. But the

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relative importance of those differences in the pharmacological response to alcohol is actually fairly -- has a fairly limited influence on susceptibility to alcoholism in Caucasians.

Q. Is there a division of areas that you could list for me that play a role in whether or not somebody could become alcohol dependent, such as genetics, personality, pharmacological effects of alcohol? Is there a category of areas that play a role in that? Forget the controversy. Are there agreed upon categories or specific items that you could take into consideration in determining whether or not somebody would become alcohol dependent?

A. Well, the heritability of alcoholism -- of susceptibility to alcoholism is estimated to be approximately 65 percent and, you know, so 65 percent is considered to be genetic and about a third to be non-genetic or environmental.

Q. What is that? Does that encompass personality?

A. That would -- the genetic factor is --

Q. No, environmental?

A. Well, genetic factors -- personality is also heritable and some of the environmental variability and susceptibility to alcoholism would be

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genetic and some would be environmental.

Q. What are some environmental examples?

A. Some environmental examples would be just the availability of alcohol, the frequency of its use for recreation, cultural attitudes toward our community, attitudes towards the appropriateness of spending time in bars.

Q. Is there any component that goes into the equating in addition to genetics and environmental factors, such as the biological effects or reactions of alcohol with the human system?

A. Well, again, biology can't really be separated from genes and environment and so part of the genetic predisposition would be to influence differences between people and specific genes that code for neurotransmitters and receptors that can be influenced by alcohol and yet there can also be environmental influences that would change the way the brain is organized or its sensitivity to alcohol just like repeated exposure or use of other substances could influence the responses to alcohol.

Q. Are there alcohol receptors in the brain?

A. No specific alcohol receptors.

Q. Are there nicotinic receptors in the brain?

A. Yes. There are receptors in the brain that

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alcohol does influence, but there are no receptors that are specific for alcohol.

Q. How long has the scientific community known that there is nicotinic receptors in the brain?

A. Nicotinic receptors have been described for a long time. I don't know actually the date of when they were first characterized pharmacologically, but it would be throughout most of the century.

Early in the century people were able to demonstrate in animals and in human material binding to nicotine.

Q. Do you know how many nicotinic receptors there are in the brain? Varieties?

A. I don't know what the latest count is in terms, but there are there are multiple types.

Q. Do you know what research Reynolds has done with respect to nicotinic receptors in the brain?

A. No, I don't.

Q. Do you know how many people Reynolds employed looking at the different types of nicotinic receptors there were in the brain?

A. No.

Q. Do you know how much money Reynolds spent looking at nicotinic receptors in the brain?

A. No.

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Q. Do you know when Reynolds first discovered how many different types of nicotinic receptors there were in the brain?

A. No.

Q. Do you know what a nicotine analog is?

A. Yes.

Q. What's a nicotine analog?

A. It's a chemical that has a shape or properties that allow it to bind to nicotinic receptors.

Q. What is the purpose of a nicotine analog?

A. To have variety of purposes, I mean an analog is something that will stimulate the same receptors so that you get a similar pharmacological effect. It could have a wide variety of applications.

Q. Do you know how much money Reynolds spent looking at nicotine analogs?

A. No.

Q. Do you know why Reynolds was looking at nicotine analogs?

A. No.

Q. Do you know what research Reynolds did with respect to nicotine analogs?

A. No.

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MR. NIMS: Is this a good place for a John break?

MR. MAISTROS: That's fine.

(Whereupon a short break was taken.)

Q. (By Mr. Maistros) Now, paraphrasing, I don't know exactly how you said it something to the effect that you don't find the nicotine dependence diagnosis to be very useful, something along those lines?

A. (Nodded head up and down.)

Q. Do you have similar problems with any of the other diagnoses in the DSM's for other drugs?

A. The criteria work fairly well for most other drugs. There are issues with many other diagnoses throughout DSM as to their validity.

Q. What is your main difficulty with the use of criteria for nicotine dependence?

A. Well, the criteria actually don't fit very well the behavior or characteristic of smokers, and that actually is explicitly acknowledged in the efforts of the DSM committee to try to force all drugs or all substances into one schema. And it explicitly refers to the fact that, for example, nicotine use does not lead to occupational and social

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impairment and yet in order to qualify for a diagnosis of dependence, the person has to first show the significant degree of clinical impairment and there's a fundamental issue as to whether or not people with cigarette smoking are mentally ill. Remember if you say that someone has nicotine dependence, according to DSM, you're saying that they have a major mental illness.

Q. It doesn't have to be major; does it? It just has to be a mental disorder?

A. No, it really is considered a major mental illness because it says that the diagnostic criteria are that you have significant impairment in clinical function and if that means that it should make a -- it should disturb your psychosocial functioning, and I feel that and most people actually, I think, agree with that. That simply is not a characteristic of most cigarette smokers. I do not consider most people who are daily cigarette smokers to be mentally ill or at least that behavior is not a mental illness.

Q. Most people agree with what?

A. That most people who smoke cigarettes daily do not conform to what we think of as a mental illness, a significant mental illness. There is no

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impairment of their cognitive function, there's no impairment of their ability to work or be productive, there's no impairment of their ability to enjoy themselves. It simply doesn't fit the basic notion of a mental or cognitive impairment.

Q. Have you reviewed any studies that have analyzed the lost productivity as a result of workers smoking?

A. The fact that someone takes coffee breaks or cigarette breaks --

Q. The question is have you reviewed any such studies? I'm not looking for your opinion. I know your opinion. I've read the five depositions. Have you reviewed any studies that have looked at the issue of lost productivity as a result of smoking?

MR. NIMS: Do you mean as a result of smoking itself or as a result of medical conditions?

MR. MAISTROS: He's testified that there's no loss of work or productivity as a result of smoking, so I'm trying to figure out the factual basis for that opinion testimony.

Q. (By Mr. Maistros) Have you ever looked at any studies that have analyzed lost productivity as a

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result of smoking?

A. Well, I have reviewed some publications that look at loss of time and time away from work in relation to cigarette smoking. Both for several reasons, just as an employer of people myself. And I can't give you a specific reference at this moment, but I have looked at such publications.

Q. Have you done any research on your own to determine if there is loss of productivity arising out of a person's decision to smoke?

A. It's a complex question that I actually have considered personally as an employer. And the issues that I came back with when I was considering our university and hospital policies about allowing cigarette breaks was that people find that when they smoke, they think more clearly.

Some people report that, and yet so that they may actually be more efficient when they are working as a result of their smoking, but then at the same time, they may take breaks that then take them away from their work. So the principle issue; that is, the relative balance between are they putting in the hours that a non-smoker puts in and what is their efficiency during the hours that they do put in. We have in balance I believe that people

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who choose to smoke may be more efficient as a result of that and as long as they're willing to put in the same number of hours of work effort, that there really is no loss of productivity.

Q. Now, my question is, what research have you done to look at the issue of loss of productivity arising out of the act of smoking? Have you done any such research?

MR. MURPHY: I'm going to object. I think that's the question he was trying to answer, so it's been asked and answered.

MR. MAISTROS: Hasn't been answered but that's the question he was asked.

MR. MURPHY: I think he was answering that answer. You may not like the answer, but that's the answer that he gave.

MR. MAISTROS: I would like an answer to the question.

Q. (By Mr. Maistros) Have you done any research in terms of lost productivity relating to smoking?

A. I reviewed the literature, I interviewed a number of employees that I had, I've talked to other people who are employers of workers, and on the basis of that, I came to the conclusion that this was not a

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simple black and white issue where you could simply say that any given -- a group of smokers as a group were more or less productive as a result of their smoking. It really does depends on what are the -- what are the policies for assuring that people put in the same number of hours of work time once you allow for breaks.

Q. Is your --

A. And --

Q. Is your research you just mentioned on your CV somewhere?

A. This is what I did as -- one of the things I considered when I was chairman of the department or Head of the Department of Psychiatry, which is on my CV. I will also consider this as a --

Q. I know your title is on your CV, is your research relating to work performance and smoking on your CV?

A. It was an administrative issue that came up in connection with my other activities as an employer.

Q. Is it on your CV?

A. Yes, sir.

Q. Where or what article?

A. Oh, it's not a research publication if

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that's what you mean. It's something that arose, as I said a couple of times before, it's something that arose out of my working functioning as an administrator and as an employer.

Q. What cigarette breaks does your employer allow at the hospital?

A. Well, at this time we've actually we've banned smoking in the hospital and people take -- can take breaks on an hourly basis. I don't know that the policy is written in hard form. I don't believe it actually is written out explicitly, but the understanding is that people are to work a specified number of hours allowing only for a couple -- two, a morning break and an afternoon break and a time at lunch, and then if there's any additional break time, that has to be compensated for by longer duration of hours spent on the job.

Q. What is not hard and fast, the break policy or the no smoking policy?

A. The no smoking policy is a hard and fast rule. The way to implement breaks is discretionary between the employer and the employee. You have to satisfy your boss that you're doing your job.

Q. And would it be your opinion that the hospital should allow more breaks for smokers because

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they increase their performance?

A. I think it's an individual issue.

Q. Would you be in favor of allowing more smoking breaks because of your belief that performance is enhanced?

A. I believe it's an individual issue that has to be negotiated between the employer and employee.

Q. But where would you lie on the issue?

A. My position is that I would have to evaluate it on the basis of my judgment about that individual, that I would not have a fixed rule for all individuals.

Q. Now, have you done any actual research, not thinking about it in your administrative role, actual research where you've studied humans to determine if there's increase in performance related to smoking?

MR. MURPHY: Objection.

MR. NIMS: Objection.

Q. (By Mr. Maistros) Where do you base your knowledge that there's increase in performance related to smoking?

A. There's a body of literature that documents the cognition enhancement effects of cigarette smoking or use of nicotine indicating that patients or individuals who do that actually think more, have

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the experience of thinking more clearly, and on objective performance tests of selective attention, sustained attention, they are better able to attend and discriminate sensory six stimuli.

Q. They're similar body or similarly related to the use of cocaine?

A. Actually, I'm not familiar with that in connection with cocaine. Cocaine generally has an intoxicating effect that's not present in nicotine.

Q. You've never interviewed or read any -- interviewed any patients or read any literature whereby the opinion has been expressed that people believe they have enhanced performance abilities when they use cocaine?

A. Low doses often there's a subjective euphoria and people find themselves stimulated and that can sometimes be described as a cognitive enhancement effect, but there's an effect of nicotine that's beyond that of euphoria and a sense of stimulation.

Q. Now, you use the word "nicotine" as opposed to smoking. Where did you learn that it was the nicotine that resulted in this cognitive enhancement as opposed to just smoking?

A. Experiments have been done both with

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cigarette smoking and with nicotine. Many people believe that nicotine is a major element in the cognitive enhancement effect of cigarette smoking. I would not conclude that it's the only one, but you can get similar cognitive enhancement effects with nicotine alone.

Q. Do you know what cotinine is?

A. Yes.

Q. What's cotinine?

A. It's one of the principle metabolites of nicotine that's found circulating in the blood. It's used as an alternative measure of what nicotine levels are.

Q. Do you know when Reynolds first began research relating to cognitive enhancement related to the use of nicotine?

A. No.

Q. Do you know how much money they spent doing that research?

A. No.

Q. Do you know how many different research projects they had related to that issue?

A. No.

Q. Do you know how many scientists they hired that did nothing but look at that issue?

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A. No.

Q. Now, when you say cognitive enhancement what does that phrase mean?

A. Specifically, it refers to the fact that patients -- that individuals are able to pay attention and to discriminate targeted and untargeted stimuli and more clearly so that they feel more alert, they feel that they think more clearly, and they may be able to process and retain more information in a shorter period of time. In other words, they're thinking better and clearer.

Q. Now, are these tests that you read were they smokers or were they people ingesting nicotine gum or both?

A. Both.

Q. What smoking studies did you read or review that led you to believe that there was cognitive enhancement related to smoking?

A. I can't refer you to a specific article, but there are many such in the literature and that material is reviewed, for example, in the book that I cited earlier, Orleans and Slade.

Q. Nicotine Addiction?

A. Yes.

Q. Are Orleans and Slade recognized

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Source: https://www.industrydocuments.ucsf.edu/docs/dxjf0001

authorities on nicotine?

A. They're certainly published experts in the field. I wouldn't say that everything that they say or have asserted as authoritative, but they're active in the field and recognized.

Q. You've relied on that publication to arrive at some of your conclusions?

A. Actually, I'm not sure exactly how you would use the word "relied." I took that as a representative summary of views that actually is somewhat parenthetical to my own conclusions, and so I studied that as an example actually of a book that tried to make the case that cigarette smoking is an addiction, a conclusion that I don't really agree with. So I don't rely on it. I actually just took it as -- to see how do people who make that ascertain what do they base it on and so I don't -- I don't really rely on that as the basis of my own conclusions.

Q. Okay. You do not believe cigarette smoking is an addiction; correct?

A. Well, it depends how you use the -- how you define the word "addiction."

Q. How do you define it when you say you do not believe cigarette smoking is an addiction?

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A. I don't -- what I think is a fact and not a matter of opinion is that cigarette smoking does not lead to cognitive impairment or the ability to think logically and reasonably. I do not believe that it leads to a consistent withdrawal syndrome. Most people who smoke can stop without having withdrawal, and if they do have any withdrawal, these are generally mild anxiety and depressive symptoms and that it does not really lead to the kind of overwhelming interference with occupational and social function that is characteristic of the popular notion of the way a heroin addict or a skid row alcoholic behaves.

Q. Okay. So you believe alcohol is an addiction?

A. I believe alcohol can be an addiction in the sense that it can lead to abuse and dependence and more specifically, when it is used frequently, it does lead to cognitive impairment and physical withdrawal that is life threatening.

Q. Okay. Now, you said that smoking is not like your skid row alcoholic. Is that a scientific term you use in your practice, a skid row alcoholic?

A. It is a term that is I think used in both the scientific literature and the lay literature and

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the reason I used a descriptor like that is that the word "addict" evokes a mental image in people of someone who is out of control and who has loss of control, and it has often been used to evoke that particular image which people find pejorative. And so in order to communicate to you why I don't feel nicotine is appropriately described as an addition, I wanted to use a term that would evoke an image in you that has an emotional content and a pejorative connotation because that is exactly what the word "addiction" is meant to do in many people's usage.

Q. Well, you don't like the word "addiction" in any context, though; do you?

A. That's correct.

Q. So it's not so much the nicotine/tobacco issue related to addiction. Philosophically you just don't like the word "addiction."

A. Well, it's more than that. The use of that word in connection with cigarette smoking is especially egregious. So it is, I think, the best example of the inappropriateness of using the term.

Q. Well, you said alcohol can be addictive. Would you say the same thing with respect to cigarette smoking?

A. I'm --

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Q. Forget --

A. I'm open to seeing a case like that, but nicotine is not -- does not have the properties of leading to cognitive impairment in doses that people generally take so that that part of the quote "addiction syndrome" does not arise at all in customary use.

Q. Would you believe that heroin could be addictive?

A. Yes, given the qualifiers that there are problems with the concept of addiction in general.

Q. Would you believe that cocaine can be addictive?

A. Yes.

Q. If you had your choice between using the phrase "cocaine addictive" and "cocaine dependent," which would you use?

A. I think the way you're asking the question no matter what answer I give you tends to give you a misleading understanding of what I believe.

Q. Well, you're free to explain your answers. You've done that.

A. Okay. I'm reluctant to say to take a forced choice between whether use of cocaine is best characterized as an addiction or not because the

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issue --

Q. Let me just make this shorter if I can. I'm not so much interested in your belief as to the definitional use of the word. I'm saying everything else being equal, would you rather somebody use the word "cocaine dependent" or "cocaine addictive"?

A. Dependent.

Q. And that would be true for heroin?

A. Yes.

Q. Morphine?

A. Yes.

Q. Alcohol; correct?

A. Yes.

Q. Or tobacco?

A. Yes.

Q. It's really a matter of and I think it's in your deposition somewhere is the connotations related to the use of the word "addictive" is what causes you problems not so much the scientific meaning of the use of the word?

A. Connotation and also the meaning that people have loss of control, loss of voluntary control.

Q. Okay. But in a patient setting it's much easier is it not for you as a practitioner to tell a

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patient he's nicotine -- I'm sorry cocaine dependent as opposed to he's a coke addict?

A. It's not that at all. It's not just a matter of being easy or whether it's pejorative connotation or not or an insult or a constructive label. The principle fundamental therapeutic issue is one of responsibility and choice and responsibility for your choices and if you tell someone that they do not have control, you allow them and you facilitate them saying oh, then there's nothing I can do about it and that's the end of the story. Whereas if you say to them you are responsible for your choice and you can stop if you want to. Do you want to? Why do you want to? Why do you not want to? Then how do you then implement that goal, whatever it is, whether you want to continue to do it or not to do it.

Q. Right, and as a philosophical matter, you believe do you not that the heroin addict, the coke addict, the alcohol addict, the heroin dependent person, the alcohol dependent person, the coke dependent person is responsible for their choice?

A. Not always because if they are currently intoxicated, then they're not able to think clearly so they need a period of abstinence before you can

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reason with them in the same way that you can always reason with someone who is a cigarette smoker. And if they have a physiological dependence, so that when they stop drinking alcohol they're going to have withdrawal seizures, then they have to be detoxified and they need to be treated with medications to allow that safe withdrawal.

Q. But if I had to characterize you philosophically whether it was cocaine, alcohol, or heroin, it's your opinion, assuming the person is not intoxicated, that that person if he's dependent on those substances has control over his decision to use those substances?

A. Well, if someone is regularly using alcohol or heroin, they will have residual impairment in cognitive function such that they do not learn well in any kind of cognitive or behavioral therapy for an extended period of time. So it's not just a matter of whether they're acutely intoxicated in this moment or in the hour that I'm having a session with them, unless they're abstinent for a prolonged period of time of a month to several weeks, they are not going to learn in cognitive behavioral therapy.

Q. Okay.

A. And so I think that they have an impairment

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of choice as a result of that intoxicating effect of alcohol that is not just acute but can be subacute.

Q. Have you done research to look at the pharmacological effects of cocaine, alcohol, and heroin on humans?

A. Have I done research on the pharmacological effects of cocaine?

Q. Alcohol and heroin.

A. I've done research on the pharmacological effects of morphine and I've done extensive clinical research on both cocaine abusers and dependents and alcohol abusers and dependents. Those are the clinical effects of alcohol are pharmacological effects. I have not specifically studied the neuropharmacology of cocaine and alcohol myself.

Q. Have you done that with nicotine?

A. No.

Q. You could not offer an opinion then on the neuropharmacological effects of nicotine on humans?

A. Well, I'm familiar with that literature and I have expertise in neuropharmacology. I'm a member of the American Academy of Neuropsychopharmacology, but I'm retained here to give expert opinion with regard to motivated behavior, personality, and psychiatric diagnosis.

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Q. As opposed to neuropharmacology?

A. Correct. Given the limits that you can't really separate biology from psychology completely, there's always a biological basis for psychological events.

Q. Do you know what research Reynolds did to determine the role that the biological versus the psychological impact that nicotine had on humans?

A. No.

Q. Do you know what compensation smoking is?

A. Yes.

Q. What is it?

A. If someone changes a brand of cigarette that has a different level of a chemical in it, like say nicotine, do they then compensate by increasing or decreasing the number of cigarettes or the frequency of cigarette smoking in order to achieve and maintain the same level of that substance like nicotine?

Q. Does it have anything to do with puff volume?

A. That could also influence -- how much you take in from a particular cigarette will also be another factor in the number of cigarettes that you smoke.

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Q. Well, does compensation smoking have anything to do with puff volume or vice versa?

MR. MURPHY: Objection; asked and answered.

THE WITNESS: Is there still a question for me to answer? I thought I had answered it.

Q. (By Mr. Maistros) Does puff volume have anything to do compensation smoking?

A. I'm sorry; I thought I had answered it.

Q. Does puff volume have anything to do with compensation smoking not number of cigarettes smoked? Is it your understanding that compensation smoking deals primarily with the number of cigarettes smoked?

A. What I believe I said in response to your question was that the amount of smoke that you take in to yourself when you're smoking a cigarette will influence the number of cigarettes that you smoke o: the frequency that you smoke if you're trying to maintain a constant chemical level of something. It's just a matter of simple algebra. If you're trying to keep one thing constant and you vary something like puff volume, then you're going to have to compensate by the number of puffs that you take and the number of puffs that you take is going to be

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a function of the number of puffs that you take in smoking a single cigarette and the number of cigarettes that you take.

Q. Do you know what puff volume is?

A. I thought that what it referred to was the amount of smoke that you took in to your mouth in any given inhalation.

Q. Do you know what draw is?

A. I'm not sure I have the exact technical way that it's defined, but I mean the notion is that the way you draw in cigarettes has to do with the force of air that you take in order to inhale and so that would influence -- the way you draw on a cigarette will influence the amount of something that you take into your mouth and inhalation.

Q. Do you know what pressure drop means in relation to smoking?

A. No, I don't.

Q. Do you know what work Reynolds has done with respect to analyzing pressure draw puff per volume in terms of taking in nicotine?

A. No.

Q. Do you know how the nicotine yields of cigarettes are determined?

A. I wouldn't consider myself an authority on

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that. I believe I have a general idea from material that I've read, and I've read -- well, I think that's an answer.

Q. And how is nicotine yield determined?

A. Well, again, I'm not speaking here as an authority, but if you're just testing my knowledge about that, my understanding is that there are issues about the way this is done in that there are machines that are used that have certain draw characteristics or pressure drop, I believe was the term you used, and that can be -- that's done in a standardized fashion. And, of course, when someone smokes an individual may vary in exactly the way they extract smoke from a cigarette, so there may not be an exact correspondence between the way this is done experimentally to standardize the procedure and the way a given individual does.

Q. Do you know what a Cambridge filter is?

A. No.

Q. Do you know what tests Reynolds did to determine actual human smoking characteristics as opposed to FDC testing method characteristics?

A. No.

Q. Do you know what research Reynolds did with the use of ammonia to affect PH in its tobacco?

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MR. MURPHY: Objection to the form of the question; lack of foundation.

THE WITNESS: No.

Q. (By Mr. Maistros) Do you know what work research Reynolds has done to determine how nicotine could be better transferred in the human body?

MR. MURPHY: Objection to the form of the question; lack of foundation.

THE WITNESS: No.

I can save you some time in that I was not retained to review specifically anything about research that Reynolds has done. I've only considered a cumulative body of literature and did not look specifically to see what Reynolds contributed or did not contribute.

Q. (By Mr. Maistros) Okay. Have you ever written any or expressed any opinions on whether or not nicotine should be regulated as a drug?

A. Yes. I wrote a statement when the FDA was considering regulations about how to classify -- was considering whether or not cigarette smoking or nicotine could -- should be regulated by them.

Q. And is that in your file that you've brought?

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A. Not in this file, but it is a matter of record.

Q. A record where, what case?

A. Well, it was submitted to the FDA.

Q. And --

A. It wasn't really a part of any case. It was not a part of this case or any other specific case, but it did -- it does happen that I did submit a statement to the FDA.

Q. Who retained you in this case?

A. R.J. Reynolds. In this case you mean or in --

Q. Hoskins and Chamberlain, who retained you?

A. Reynolds.

Q. Who's paying you?

A. I'm paid by Jones Day.

Q. Who is Jones Day?

A. Jones Day is the law firm in Cleveland that I believe is retained by Reynolds to represent them in this matter.

Q. And who asked to you write the letter to the FDA?

A. I believe I was asked by Mr. Nims.

Q. Who is Mr. Nims?

A. Mr. Nims is the attorney to my right, who

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is in Jones Day Law Firm.

Q. And were you given any suggested ideas for the content of your letter to the FDA?

A. No, I was told what the FDA was considering and asked if I wanted to submit a statement or not. I wasn't told what to say or whether I even had to say, just whether if I wanted to take the opportunity to make a statement that I could and they would make sure it got in.

Q. Who did you write it to?

A. I believe it was actually addressed to Mr. Kessler, who was at that time the FDA director.

Q. And did you read a draft of it before you sent it to Mr. Kessler -- did you read a draft of it to Jones Day or Reynolds?

A. No, I didn't.

Q. And what research did you do -- by the way, what opinion did you express in your letter?

A. Actually, I think the statement to the FDA was similar to my statements in these two cases. Although it did not refer specifically to any individual cases, the overall issues of the history of the terms, the use of the terms "addiction" and "dependence" was the primary focus of that statement, and those opinions are represented in these

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statements.

Q. Did you have any comment upon whether or not nicotine itself was a potentially drug dependent-producing drug?

MR. NIMS: If you recall.

THE WITNESS: Yeah.

MR. NIMS: All this is if you recall.

THE WITNESS: I do recall that the discussion included the fact that there were changes in diagnoses from DSM-III to III-R between the use of the term "tobacco dependence" and "nicotine dependence." There was to my knowledge -- to my recollection I did not specifically comment on nicotine as a separate chemical substance but was primarily concerned with tobacco smoking.

Q. Were you paid by Jones Day or Reynolds to write this letter?

A. Let's see. I'm trying to remember. I believe that I did receive some compensation for my time spent in preparing the statement.

Q. Now did that compensation go to the hospital or to you?

A. I actually don't recall.

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Q. Is that the type of compensation you can receive and keep yourself?

A. Yes.

Q. Are there any internal guidelines at the hospital whereby you have to go through a conflicts boards or review committee before you can agree to accept an outside position or agree to testify in a case such as this?

A. I don't have to go through a conflict board prior to doing something, but periodically we do report to a conflict of interest review committee all of our activities.

Q. Did you advise the FDA you were paid to write your letter?

MR. MURPHY: Objection to the form of the question.

THE WITNESS: I actually don't remember.

Q. (By Mr. Maistros) Did you advise the FDA that you had been retained by a law firm to write your letter?

MR. MURPHY: Objection to the form of the question and for lack of foundation.

THE WITNESS: I actually don't remember.

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Q. (By Mr. Maistros) Did you tell the FDA that you were paid by agents of Reynolds to write the letter?

MR. MURPHY: Objection to the form of the question and for lack of foundation.

THE WITNESS: The statement was submitted as a compilation of statements that was submitted by a group of tobacco firms, and so it was very clear and obvious that the statement was not a spontaneous, isolated statement from me as an individual alone but that it was a part of a collection of statements that had been put together by the tobacco industry.

Q. Is it fair to say that you were against the FDA's regulation of nicotine?

A. I don't believe I -- I don't recall actually addressing myself to that specifically. I really tried to summarize what I saw as the scientific facts regarding the difficulties and limitations of the concept of addiction.

Q. Would you view your letter as pro tobacco or anti tobacco?

MR. NIMS: Objection.

THE WITNESS: Again, I tried to address

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the scientific facts and just let them fall where they may.

Q. (By Mr. Maistros) Did you --

A. So I don't believe that it has a bias.

Q. You don't believe that it has a bias because you're paid by a tobacco interest to write the letter?

MR. MURPHY: Objection to the form of the question.

THE WITNESS: Would you repeat the question?

Q. (By Mr. Maistros) You don't believe it has a bias because you were paid by tobacco interest to write the letter?

A. No, I don't believe I was biased because I was paid.

Q. What position was tobacco taking on whether or not nicotine should be regulated?

A. I don't think that they were in favor of it. I don't think -- I'm not sure that that was actually a part of my statement. I was simply trying to testify as to the facts.

Q. The definitions of addiction?

A. Yes. What the words mean.

Q. Have you ever heard of John Robinson?

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Source: https://www.industrydocuments.ucsf.edu/docs/yxl0001

A. I can't remember offhand.
Q. Did you ever hear of Walter Pritchard?
A. I don't remember.
Q. When was the first time you ever did any paid work for tobacco?
MR. MURPHY: Objection to the form of the question.
THE WITNESS: Tobacco starts handing out money, I'd like to get some.
MR. NIMS: I assume you mean retained by lawyers you understood to be representing the tobacco company?
MR. MAISTROS: I didn't want to ask 15 questions. We can do it that way if you want.
Q. (By Mr. Maistros) When was the first time you were paid by Jones Day?
A. Okay. The first -- the first case in which I had any testimony in a tobacco-related case was 1993.
Q. What case was that?
A. Cooper versus I'm not sure exactly what the companies but RJ Reynolds was one of them, but I think it was several.
Q. And you were paid by Reynolds?

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A. Yes.

Q. Or Jones Day?

A. It was Jones Day.

Q. Have you offered testimony on behalf of any one other than Reynolds?

A. I believe my testimony has been -- payment has always been through Reynolds but often there have been -- there have been cases in which there were other defendants and I was used as an expert. I'm not sure exactly how the Jones Day Law Firm apportions those costs. It hasn't been something I was concerned about. I always just focused on the facts of the individual case.

MR. MURPHY: Jack, for clarity your firm is counseling Constano and you know that Dr. Cloninger was used in the Constano case?

MR. MAISTROS: Was that before Cooper?

MR. NIMS: No.

THE WITNESS: No.

MR. MAISTROS: Okay. What was the next case you testified in? I'm sorry that's where you're attempting to clarify.

MR. MURPHY: To clarify whether he testified or submitted reports or whatever

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the question was on behalf of anyone but Reynolds.

MR. MAISTROS: I assume we'll get to that when we go through these cases.

MR. MURPHY: That was your question and in case his answer didn't comprehend that --

MR. NIMS: I --

MR. MURPHY: Constano (ph) was one of these cases.

MR. MAISTROS: I thought his answer was very accurate that he has always had his bills paid by Jones Day, but there have been cases in which there were defendants other than Reynolds.

THE WITNESS: I believe that I've been endorsed or accepted as a defendant as an expert by multiple defendants in some of those cases. I actually don't know the details of that process.

My concern as a clinician and as an expert is only to focus on the individual case and I really don't concern myself with, you know, who is the original client, who's paying it.

Q. After Copper what was the next case?

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MR. NIMS: These are cases in which he has --

MR. MAISTROS: He's been retained to testify.

MR. NIMS: -- given testimony?

MR. MAISTROS: He's been retained, whether he's testified or not.

THE WITNESS: You know, I wasn't asked to bring a list of all those cases.

Q. I'll give you these. You tell me if you were retained; okay?

A. Okay.

Q. Rogers?

A. Yes.

Q. Conners?

A. I don't remember that one.

Q. Chamberlain?

A. Yes.

Q. Hoskins?

A. Yes.

Q. Arch or Barnes?

A. I don't remember that.

Q. Pennsylvania?

A. I don't think so.

Q. Any of the Medicaid/Medicare cases?

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Source: https://www.industrydocuments.ucsf.edu/docs/ytxl0001

A. Some.
Q. Which ones?
A. Hum.
Q. Mississippi? Texas?
A. Texas.
Q. Any other Medicaid case? Florida?
A. I didn't do anything on that one I don't recall, that I recall. I remember discussions about it, but I don't certainly didn't have much role in it.
Q. Any other individual cases you can recall? Obviously, Constano was one you were involved in; correct?
A. Yes, Constano. Let's see.
Q. Any other states that pop in your mind?
A. Just trying to think offhand. We talked about Texas, Constano.
Q. Minnesota?
A. No. Washington DC, District of Columbia, that's the only other one I remember.
Q. And in each of these cases have you offered similar opinions, such as New York and Ohio; that is, cigarette smoking shouldn't be classified as an addiction?
A. Yes, my opinion has not changed across

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Source: https://www.industrydocuments.ucsf.edu/docs/vjxl0001

these cases.

Q. Have you ever seen a class definition that you've agreed with in any of these cases that you've been retained by the tobacco companies?

A. I think the whole approach of class definition is problematic, and I have not because the whole issue is the need to look at individual facts and individual cases and that's actually part of our official standards dictated by the DSM-IV, III and IV.

Q. And is it part of your belief that you couldn't -- even if you accepted the term "addiction," you couldn't diagnose somebody as being addicted unless you actually had an examination of that person?

MR. NIMS: Objection.

THE WITNESS: Well --

MR. MAISTROS: Let me strike the question.

Q. (By Mr. Maistros) If you wanted to make a determination if somebody was nicotine dependent, is it your belief that you should interview that person one on one?

A. Not necessarily. It's -- you want to have comparable information from what you could obtain in

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a personal interview and so it really does depend if there are extensive medical records and an accurate and thorough review of the person's life and personality and attitudes and situations and feelings, then it's possible to make a meaningful and valid diagnosis without a personal examination by you yourself, but the same quality of information that would be obtained in a direct interview would need to be available.

Q. Now, the cases you cited that you've been retained to assist the tobacco defendants in, have you actually provided trial testimony in some of those cases?

MR. MURPHY: Objection to the form of the question.

THE WITNESS: Yes.

Q. (By Mr. Maistros) Which ones would those be? Cooper, Rogers, any others?

A. Let's see. Cooper --

MR. NIMS: Off the record.

(Off the record.)

(Back on the record.)

Q. (By Mr. Maistros) So just Cooper for trial testimony?

A. Yes, I believe that's right.

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Q. Have you totaled the compensation you've received in the seven cases you've identified --

A. No, I haven't.

Q. -- plus the FDA?

A. No, I haven't.

Q. Have you submitted invoices for any of the seven cases?

A. Yes.

Q. Which ones?

A. Gee, I'm sure I did for Cooper and Constano, Texas. I have not for as yet for Chamberlain or Hoskins. Those are the only ones I recall at the moment.

Q. And have you totaled the invoices that you've sent in for Texas, Constano, and Cooper?

A. I don't have any idea. Those funds go to -- I don't keep those funds.

Q. How much did you get paid for your FDA letter?

A. I think that was --

MR. MURPHY: Objection to the form of the question; lack of foundation.

THE WITNESS: I honestly don't remember, but it was not a lot of hours. I mean I always charge on the basis of an

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hourly rate.

Q. (By Mr. Maistros) Is that still true today?

A. Yes.

Q. What is it $300 an hour?

A. Actually, there's an error that I wanted to correct. It does say $300 an hour in my Chamberlain statement, and it should be $350. $300 is the rate up to 1996 and as of 1997, it went up to $350 and I just didn't.

Q. Fifteen or fifty?

A. 350, $350 an hour. That was a change as of this year. That's based on the standard departmental fee.

Q. And you've mentioned you were chairman of your department?

A. Yes.

Q. When did you become chairman?

A. 1989.

Q. And have you been chairman since then?

A. I did it for five years.

Q. Is that the term?

A. There's no fixed term. It's annually renewable.

Q. When did you cease becoming chairman?

A. 1994.

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Q. Was it voluntary?

A. Yes.

Q. What is the status of the audit at your department?

A. What audit?

Q. The audit you testified about in Constano and several other cases that was going on.

A. That was completed.

Q. What was the finding?

A. There were no irregularities that were of any major problem. It was -- the audit company I think found nothing that it could question within about 2 percent of all the charges and anything that was considered arguable was corrected.

Q. How much was paid back?

A. I honestly don't know the exact amount.

Q. Is there a report that was placed in yours or anyone else's file concerning that audit?

A. Not in mine.

Q. Who at Washington University had the most knowledge concerning that audit?

A. The dean.

Q. What's his name or her name?

A. William Peck.

Q. Current dean?

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A. Yes, he's still the dean.

Q. Okay.

(Whereupon a lunch break was taken.)

Q. (By Mr. Maistros) Now, I was looking at my notes, this isn't a memory test I just want to make sure the record is clear. Have you testified as an expert in Burton? I don't think I listed that when I was listing.

A. Yeah, I gave a deposition in Burton.

Q. No trial testimony?

A. That's correct. Well, there hasn't been a trial.

Q. Of the cases you've identified you've testified in, they were all on behalf of Reynolds or some other tobacco company?

A. Correct.

Q. Have you ever testified on behalf of a plaintiff against a tobacco company?

A. No.

Q. Now, if you could look at Exhibit 3, which is your CV, it should still be in front of you.

A. Oh, right.

MR. MAISTROS: Dennis, I do have another one of these if you don't have one.

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MR. MURPHY: No, I have one.

Q. (By Mr. Maistros) On the first page underneath present position you list Professor of Genetics and Psychology?

A. Yes.

Q. Does that mean you teach genetics and psychology? Are those two courses or one?

A. Actually, those are appointments as Professor of Genetics and Professor of Psychology, and I have joint appointments in both departments and I do teach in both at times.

Q. Do you -- in those courses do you teach anything related to nicotine or nicotine dependence?

A. No.

Q. Are those the only two titles you have in terms of teaching?

A. Psychiatry, genetics, psychology, also by virtue of the genetics appointment have an appointment in the division of biology and biomedical sciences and give lectures in biology as well.

Q. Do any of those lectures involve nicotine or nicotine dependence?

A. No.

Q. And similarly for your position at --

A. Well, you know, I should say that I don't

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believe I have ever given a lecture in those departments that did concern it. I could certainly imagine that discussions of cigarette smoking could be used as examples or points about motivated behavior, but I actually have not done that at this point.

Q. So although nicotine dependence could be the subject of your lectures --

A. It has not been.

Q. It hasn't been?

A. That's correct.

Q. Would that be true for all of your titles, psychiatry, genetics, psychology, biology?

A. I have discussed cigarette smoking and nicotine dependence in the course of lectures and seminars in psychiatry.

Q. And this is at Washington University or third parties or what?

A. I have done that at NIDA and at NIAAA and in lectures that I've given at various places.

Q. Have any of these lectures actually been published?

A. No. You have a list of all the publications.

Q. But when you give lectures do you have

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outlines of your lectures?

A. I generally don't. Actually, what -- I use material from my published papers.

Q. How often have you lectured on smoking or nicotine?

A. Well, in the last year I actually have talked about that several times. Specifically, that I can remember, I've discussed that at recent meetings at the National Institute of Health both in connection with drug abuse, NIDA, and NIAAA and let's see, I think in the other places it has been less formal and more in response to questions.

Q. Were any of your primary topics at your lectures where you spoke about tobacco and nicotine tobacco and nicotine as opposed to some other topic?

A. No, it would be as a part of a more general approach to personality or psychopathology.

Q. Have any of those lectures involved your opinion as to the changing definition of addiction insofar as cigarettes and nicotine is concerned?

A. That has been discussed in psychiatry lectures with residents in psychiatry.

Q. Now, I want to get some phraseology down so I'm not misusing words. When I use the word "nicotine dependence" do you understand it to mean in

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the context of the DSM's?

A. That would be my first guess. Is that the way you want to use it? Because are there other definition.

Q. The other definitions are what ICD?

A. Uh-huh.

Q. Number 10?

A. Uh-huh.

Q. Is that similar to the DSM-IV?

A. It's similar. It adds a craving item that is missing in DSM-IV but basically otherwise it's fairly comparable.

Q. Well, the craving item that's added in ICD-X is one of a multiple options you can use to determine if you're nicotine dependent; correct?

A. Correct.

Q. It's just another criteria --

A. It's another one.

Q. -- to take into consideration?

A. Right.

Q. It's not necessarily a difference in definition of nicotine dependence? Don't both of the DSM-IV's and ICD's give you a range of things to choose from?

A. Correct.

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Q. And if you hit so many in a certain amount of time, you're nicotine dependent?

A. Three of seven or three of eight.

Q. And the ICD's again were by World Health Organization?

A. Yes.

Q. Of which you've been a consultant?

A. Yes.

Q. Have you ever written to the World Health Organization to tell them that you have difficulties or problems with their ICD number 10?

A. No.

Q. Have you done that -- the DSM's, those are established by the American Psychiatric Association?

A. Yes, right.

Q. Of which you're a member?

A. Right.

Q. Have you ever written to them to tell them that you have a problem with their DSM as it relates to nicotine dependence?

A. I was co-chair of one of the DSM-IV committees and in the overall task force of DSM, I voiced the opinion that only a small proportion of all the categories in DSM actually are valid in terms of having a substantial research basis to justify the

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http://legacy.library.ucsf.edu/tid/elo72e00/pdf Source: https://www.industrydocuments.ucsf.edu/docs/fvxl0001

criteria. And certainly nicotine dependence would not be among the ones that have been well validated. So that general opinion was expressed. I did not write specifically with concerns about those criteria. The committee I knew was already aware of the limitations because they acknowledged them in their own text.

Q. And the DSM-IV as it relates to nicotine dependence was a criteria that was established by a consensus of the committee?

A. Correct.

Q. As was the ICD number 10?

A. Correct.

Q. Have you ever lectured on nicotine receptors?

A. No.

Q. Now, in the course of your teaching, let me see how you described it, well, we've got 15 percent for teaching other doctors and 10 percent for lecturing; is it fair to say 25 percent of your time is teaching if you combine those?

A. Yes.

Q. In the course of your teaching whether it be students or doctors do you lecture on nicotine?

A. Not nicotine as a distinct pharmacological

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agent, no.

Q. In the 55 percent of your time you spend on direct research what percent is spent on nicotine?

A. Again you're distinguishing nicotine from cigarette smoking and smoking behavior and so on; is that right?

Q. Yes. Yes?

A. None.

Q. Have you done any scientific research, I'm not talking about literature review, scientific research, bench level research on the interaction of the nicotine and human body?

A. Only the supervision of graduate student doing work on human nicotinic receptors.

Q. Well, those were on nicotinic receptors. Did they actually involve research on nicotine itself?

A. Well, it was a nicotinic receptor not nicotine itself. The work was done at a DNA level rather than pharmacological challenge.

Q. What is pharmacodynamics?

A. It has to do with patterns of change of pharmaceuticals, generally in the human body, as a function of distribution, metabolism, and affinity and release from receptors.

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Q. And have you done any research on that insofar as nicotine is concerned?

A. No.

Q. What is pharmacokinetics?

A. Again, it has to do with changes in binding and affinity release of pharmaceuticals, that synopsis.

Q. And the only thing that you've ever done that touched upon that was supervising graduate students in about 1990 insofar as nicotine was concerned?

A. Correct.

Q. Okay. When we go back to nicotine dependence as defined by the DSM's, you will agree will you not that there are people that are nicotine dependent?

A. There are people who meet those criteria in DSM-IV, yes.

Q. Are there DSM-IV criteria that apply to substances other than nicotine?

A. Yes.

Q. And does the DSM refer to all those substances as being dependent producing?

A. Correct.

Q. Is there a subcategory of dependent

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/qxyl0001

producing substances that are referred to as addictive?

A. No.

Q. Was there ever under the DSM's?

A. Yes, I believe in DSM -- I'm not sure about I, but I think in DSM-II there was alcohol addiction or the term "addiction" had been used before DSM-III, not for all substances and not for tobacco or nicotine but with some things like alcohol or heroin.

Q. Are you familiar with the distinction in the '64 surgeon general's report between addicting and habituating?

A. Yes.

Q. And what was that distinction?

A. Principle -- actually, that's described in my report -- the principle --

Q. Would that help you if I gave you your report?

A. It's not necessary.

Q. All right.

A. Its essential distinction is that in order to -- the distinction between habits and addiction is that an addiction in addition to involving repetitive use, there is intoxication that impairs cognitive function, there is a physical dependence with

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withdrawal syndrome, there is an increase -- a need to increase the dose in order to get the same pleasurable effect.

Q. You're talking about -- you're talking about addiction as opposed to habit forming?

A. Correct. These are all the characteristics that distinguish an addiction in DSM -- according to the 1964 surgeon general's report from habituation or habits. Let's see, so I said cognitive dysfunction, increasing dosage, physical withdrawal, intolerance. And generally that's tolerant -- well, I already said increasing dose; didn't I? Okay.

Q. Now, are you aware also that the '64 report categorized nicotine as either habituating or addicting?

A. Categorized it as a habit.

Q. What other type of things did that '64 report characterize as a habit? What other substances?

A. I don't specifically remember that.

Q. Do you recall that heroin was categorized as habit forming --

A. Well --

Q. -- by the '64 report?

A. I do not remember that.

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Q. How about cocaine?

A. I'm not sure whether cocaine was really discussed in that framework. Both heroin and cocaine, though, are known to be intoxicating and to involve tolerance, and heroin certainly was well known to have withdrawal. So I think by the criteria of the '64 report, everything that we know about those substances would indicate that heroin and alcohol would be the models of an addiction.

Q. And I'm sorry, how about cocaine? That's how you started your answer.

A. Well, cocaine is somewhat problematic in that withdrawal patterns from cocaine usually involve on cessation there being a depression. And that has been a matter of debate as to whether that should be considered a withdrawal syndrome. There have been times when it was said that cocaine did not have a withdrawal syndrome, that this was just a offset depression, but now it's more often considered that that is, in fact, a withdrawal.

Q. So again --

A. Cocaine could have, depending on how you wanted to apply the criteria, there could be reasonable debate about whether to put cocaine in or not, but it always had the feature of tolerance and

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intoxication.

Q. And amphetamines do you know where they fit in the '64 report?

A. It would be like cocaine.

Q. As addictive rather than habit forming?

A. Correct.

Q. Now, if you assumed for the sake of my question that cocaine and amphetamines were listed as habit forming in the '64 report, could you explain how they could end up as addicting?

A. Well, that's what I was just referring to, that there was has been controversy about whether to consider the depression that's seen after people stop using cocaine and amphetamines as a withdrawal syndrome or not.

Q. Okay. But in the '64 report it's your belief that they were listed as habit forming as opposed to addicting?

A. I actually didn't make a specific judgment about what was reported there. I don't remember that specifically, but what I'm saying is that if you apply the criteria to what we know now about those substances or what was known then about those substances, that they would both tend to satisfy the cardinal features of an addiction rather than a

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habit, and the only thing that's missing is that -- is the issue of withdrawal.

Q. Okay. Now, you would never classify nicotine as addicting because, among other reasons, there's no withdrawal symptoms in your opinion or minimal?

A. The withdrawal symptom, a key feature is that the withdrawal symptoms are not consistent. Most people don't have substantial impairment when they stop cigarettes. And when that does occur, it is not of the same severity level as say, alcohol withdrawal, which is actually life-threatening.

Q. Is it a fair characterization to say one of reasons you would not classify nicotine as addicting is because it does not have substantial withdrawal effects related to its use?

A. Well, the word "substantial" is subject to some judgment, and so the severity of it is part of it, but the consistency is the other part. That, in fact, most people don't have withdrawal so that -- and the ones that do have certain personality features that are associated with anxiety proneness and so I see this more as a reaction to a change in patterns of behavior or like a psychological stress than withdrawal from a physiological dependence,

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which is uniform and consistent across individuals.

Q. What research, not literature review, research have you done on withdrawal symptoms related to nicotine?

A. I conducted the survey described in this article and then a follow-up one year later, that's referred to in my Hoskins statement, of a general population sample. Started out with 800 individuals representative of the general population, then one year later I did a follow-up on two-thirds of those individuals -- I'm sorry, three-fourths of those individuals. It was a little over 600 individuals then, and all of those people were asked questions about whether they've ever smoked, how much they had smoked, what their patterns were, whether they ever had withdrawal symptoms, and I found I was able to evaluate the incidents and the characteristics of withdrawal literature and population sample from that study.

Q. Are you talking about Exhibit 4?

A. Correct. That describes the initial sample.

Q. How many of these people did you interview?

A. All of them received a self-report questionnaire.

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Q. And you could tell from that self-report questionnaire whether they had experienced withdrawal?

A. Correct.

Q. You didn't have to see them face to face?

A. Correct. These are -- in other words, these are research subjects who were paid to cooperate in a study. We found that this is a reliable questionnaire procedure and that these people had no bias, no reason for bias, and so we can consider their results as a group to be reliable. To draw a conclusion on any particular individual, I would have preferred to have a direct personal interview, but if we just want to give the descriptions of a group, then this is considered a reliable methodology.

Q. Where in your paper does it outline the withdrawal symptoms that people experienced?

A. That is not in that paper. I do have information about exactly what questions people received and so on.

Q. What questions were there related to withdrawal?

A. If you pass this back to me.

This is the questionnaire that was

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sent, and these are all the questions about cigarette smoking. This question is one that asks about whether people had had substantial impairment and then the questions just below that top of that page list the DSM-IV withdrawal symptoms.

Q. Okay. You've identified a blue booklet, National Health Study II Lifestyle and health; correct?

A. Yes.

Q. And you pulled this out of Hoskins or Chamberlain?

A. Hoskins.

Q. We'll mark the whole file in a minute and you've turned to page 23?

A. Is that the number? Yes.

Q. And this was done when?

A. That survey was done in the summer of 1995.

Q. And it was three-quarters of 800 people?

A. Yes, a little over 600. I think it was 622 individuals.

Q. You said summer of --

A. '95.

Q. And how did you determine who to send this questionnaire to?

A. This was a sample chosen to be

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Source: https://www.industrydocuments.ucsf.edu/docs/vjxl0001

representative of the St. Louis metropolitan area based on demographic characteristics.

Q. And what did you hope to learn by asking these questions relating to cigarette smoking?

A. The questionnaire as a whole was done as part of a normative study of personality and the relationship of personality to lifestyle choice. And one of the things that is generally considered in epidemiological investigations as a lifestyle choice is cigarette smoking, and I wanted to get all the answers to the questions on pages 22 and 23 about everyone in a general population sample, so that I would have information about the incidents of ever smoking and continuing to smoke and stopping smoking and the problems associated with that.

Q. And you have at the beginning, on page 22, four questions related to smoking and I'll read them for you. Have you ever smoked cigarettes? Yes or no. Have you smoked at least 100 cigarettes -- first of all, have you ever smoked cigarettes? How many people responding smoked out of your 622?

A. 71 percent of people report that they have smoked ever.

Q. Next question. Have you ever smoked at least 100 cigarettes in your entire life (5 packs =

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100 cigarettes)? Yes or no. How many did that?

A. My recollection is that it's about 58 percent.

Q. Of the of 622?

A. Of the 622.

Q. Not 58 percent of the 71 percent who smoked?

A. No, that's correct 58 percent of the total.

Q. Smoked more than a hundred?

A. Uh-huh.

Q. So we're about 350 or so; right?

A. Right.

Q. Have you ever smoked one or more cigarettes daily for a year or more? What percentage was that?

A. About 46 percent of the general population, of the 622, have ever smoked daily in their life time.

Q. So we're about down to 311 people. Have you smoked any cigarettes during the past six months?

A. My recollection is that that's approximately 32 percent.

Q. Okay. How did you or why did you arrive at a figure of have you smoked at least 100 cigarettes in your life?

A. That is a way that the question is asked in

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/vtxl0001

epidemiological surveys in the State of Missouri, and I wanted to have -- the way to define someone as ever smoking varies across studies -- and I wanted to use it in the multiple. I wanted to ask questions about the different ways that it has been defined and in the same population, so that I knew the relationships. And that's why I asked all four of those because are different ways that people talk about someone being a smoker. Sometimes they mean that they're currently smoking; sometimes they mean that they're a daily, regular smoker; sometimes they mean that they've smoked five packs in their lifetime; and sometimes they mean they've only had a single cigarette in their whole life.

Q. And why did you use the criteria have you ever smoked one or more cigarettes daily for a year or more?

A. A lot of statistical descriptions of smoking behavior does take as its base people who have ever smoked daily.

Q. Okay. But you didn't -- the fact that they answered no to that question you didn't care that they filled out the rest of the questionnaire related to smoking; did you?

A. If they said no to that, actually, we gave

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the instruction that the remaining questions we intended them -- we thought they would only be meaningful if they had been daily smokers.

Q. Meaningful for what? What was the end goal of your cigarette smoking questions?

A. Well, then the other questions that follow have to do with some of the features of the Fagerstrom criteria for nicotine dependence and the DSM-IV for nicotine dependence and withdrawal.

Q. When you --

A. So we took as our base then those people who might be considered to have features of dependence, those people who had ever been daily smokers.

Q. The universe -- before you even asked anybody whether or not they had withdrawal symptoms related to smoking, you wanted to make sure that they were daily smokers?

A. Yes.

Q. You thought the fact that they smoked a cigarette, at least a cigarette, a day for a year was significant?

A. Correct. Because that gave me a comparison to a lot of other work in the literature.

Q. Now, was one of the purposes of this

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questionnaire to determine which of these smokers had experience withdrawal symptoms?

A. Correct.

Q. Okay. Was one of the purposes to determine if these smokers were dependent upon cigarettes?

A. Yes.

Q. And of the --

A. By varying definitions.

Q. By varying definitions. Definitions you chose from the universe of conceivable definitions you could have chose from you picked a combination of what was thrown in DSM-IV's?

A. Correct.

Q. Was all of DSM-IV incorporated or all of Fagerstrom?

A. Yes.

Q. So you, in fact, used both of those criteria?

A. Right.

Q. Why did you use both?

A. I wanted to see how they were related to one another.

Q. In a broad sense, did your results suggest whether it was DSM-IV or Fagerstrom, that they were pretty consistent findings? Was one better than the

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Source: https://www.industrydocuments.ucsf.edu/docs/YMX0001

other?

MR. NIMS: Objection.

THE WITNESS: I wouldn't say that you could say one is better than the other. What I can say is that the DSM-IV definition of dependence is the most inclusive and that of the people who are daily smokers, approximately 50 percent meet the DSM-IV criteria, whereas about 20 percent of daily smokers meet the Fagerstrom criteria.

Q. When you use the DSM-IV criteria in putting together this questionnaire your goal was to use a benchmark, if you will, the DSM-IV, to determine if somebody was dependent upon cigarettes?

MR. MURPHY: Objection.

THE WITNESS: Well, I didn't actually say that because what I've said is that I'm measuring -- I'm setting out to measure in a general population sample, those people who satisfy the criteria. I don't know that I would want to stay that the DSM-IV is a gold standard for anything because I don't think it's been well validated, but they are criteria that are frequently used. They are a part of our official classification

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/dyd0001

system, so I wanted to know how much of a relationship is there between Fagerstrom, which is another approach that's more popular among psychologists, and the DSM-IV, which is more popular among psychiatrists; and I wanted to know the relationship of those to other terms like have you ever been addicted and to preparing definitions of current and of daily use.

Q. All right. Now, there were these 24 questions, you sent out insofar as cigarette smoking is concerned?

A. I'm sorry, yes, sir.

Q. And there were only 24 questions that were answered insofar as cigarette smoking is concerned; correct?

A. That's correct.

Q. And most of these I see are yes, no; correct?

A. Yes.

Q. And if you chose to, you could have just sent out just the DSM-IV criteria; correct?

A. Yes.

Q. As part of your survey?

A. Yes.

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Q. How many questions would you have eliminated if you would have just used DSM-IV?

A. Can I see the questionnaire? Again, my feeling was that none of these criteria is really a standard and so what we needed -- what I needed to know, what I wanted to know, is what is the relationship of them.

Q. I understand that, but let's assume that you had decided just to send out questions based on DSM-IV. How many questions would you have asked?

A. I could have only asked 10 questions instead of 24.

Q. And when you got response to those 10 questions -- are those yes or no?

A. Yes.

Q. When you got responses to those 10 yes or no questions you could determine a percentage of people you believe that would be nicotine dependent at least as far as DSM-IV defines them?

MR. NIMS: Objection.

THE WITNESS: Well, it wouldn't really fully -- this kind of questionnaire doesn't really fully satisfy the DSM criteria. It would set a minimum standard because the DSM also requires you to make a judgment; that

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is, there overall substantial impairment of personal and social functioning, and it would also -- it also requires documentation that the self-reports are accurate and meaningful.

Q. (By Mr. Maistros) So was it your testimony that you could not make an educated guess or opinion as to how many of these people you surveyed were actually nicotine dependent based upon their answers?

A. Well, see, in this setting where there's -- this is a pure research study where no one has anything to gain or lose by their questions. The feeling is among epidemiological researchers that for conclusions about groups, when the group as a whole is unbiased, that even though there may be errors in individual cases, that those aren't going to be systematic biases and so basically, you assume or you can take for granted that these are probably going to be characteristic of the population.

Now, if you were dealing with a forensic client or a plaintiff in litigation or a potential plaintiff in litigation, you would have to worry that they might have something to gain or to lose by their answers and so you would then have to have corroborating evidence because of the potential

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systematic bias. In the absence of a systematic bias, I can take these answers as telling me information about patterns of relationship and I don't actually then have to make a DSM diagnosis, but I can say the people who give me the characteristics that would satisfy the minimum criteria, there are this many of them and those have you know so much of this and so much of that, so I can draw some conclusions without actually having to make a formal DSM diagnosis.

Q. My question -- again, listen very carefully. The people that responded to the survey sitting in front of you, could you determine based upon their responses whether they were nicotine dependent?

MR. NIMS: Objection; asked and answered.

THE WITNESS: I believe -- it's hard to answer you better than I already have because when you ask me the question I have the feeling that you think that there is something that anyone can tell you is nicotine dependence, that there's some gold standard, that there's some pathognomonic sign or indicator. And what I'm saying is

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Source: https://www.industrydocuments.ucsf.edu/docs/vfxl0001

we actually don't have anything that is the definitive basis for the diagnosis of nicotine dependence.

Q. That's a sufficient answer. If you want to say that won't tell you if they're nicotine dependent, feel free to say that.

A. What it can tell you is that did they satisfy a certain set of criteria that have been proposed as a standard.

Q. Let's make sure we're all clear on this. I'm not quarreling with you. You can have whatever view you want on DSM-IV and nicotine dependence. Everyone in this room can. Let's except for a moment that you sent out a criteria that listed those DSM-IV criteria and you asked a series of questions and you got answers back. I assume that wasn't a fruitless exercise?

A. Correct.

Q. You were attempting to learn something.

A. Right.

Q. Isn't it one of the things you were attempting to learn was how many people you sent these questions out to fit the DSM-IV nicotine dependence criteria?

A. Yes.

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Q. Somewhere back in your answers I believe we were at approximately 300 people or so fit the DSM-IV nicotine dependence criteria; correct?

A. Yes.

Q. So assuming you were one of those people in the universe that believe that DSM-IV's have some value, the conclusion you can draw from your survey at least is that 50 percent of your respondents are nicotine dependent.

MR. NIMS: Objection; mischaracterizes --

Q. (By Mr. Maistros) I'm just asking you. Tell me --

A. Well, the way -- I agree with the way you said it just a moment ago which was that 50 percent -- about 50 percent of them satisfied the diagnostic criteria of DSM-IV for nicotine dependence. I prefer to say it that way.

Q. I don't want to argue that any more, Bob. I'll accept that. You obviously don't agree that those criteria establish nicotine dependence --

A. Correct.

Q. -- in any setting?

A. Correct.

Q. Regardless of the findings?

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A. Correct and especially without independent corroborating evidence.

Q. Interviews, patient histories, everything?

A. Right.

Q. But even if you had all those, you're of the opinion that the DSM-IV for nicotine dependence really has limited value?

A. Correct.

Q. Okay. I'm accepting that, so I use the term at least when you did this survey you learned or opened to learn what percentage of the population satisfied the DSM-IV nicotine dependence criteria? Let's not get into whether or not they were dependent?

A. We're in good agreement there.

Q. 300 or some people satisfied the nicotine dependence criteria; correct?

A. Correct.

Q. How many of those 300 or some odd respondents also satisfied the nicotine withdrawal criteria of DSM-IV?

A. 32 percent of people who are daily smokers indicated that they had had trouble working or enjoying their usual activities, and 17 percent actually then had indicated that they had enough

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Source: https://www.industrydocuments.ucsf.edu/docs/dvxl0001

problems that they would meet the DSM-IV criteria for withdrawal.

Q. Let's make sure we're still talking about the same 32 percent universe. You're saying 32 percent of the respondents or 32 percent of the 300 and some that said or that qualified as being under DSM-IV for dependence?

THE WITNESS: Let me just double-check my denominator just to make sure I say it right. Yeah, 32 percent -- well, 17 percent of the people who were daily smokers when they stopped reported symptoms -- reported symptoms that meet the criteria for withdrawal, 17 percent.

Q. But --

A. That's based on those who are daily smokers.

Q. I don't want to be talking apples and oranges here. We've got us down to the 300 and some. Was it not those minimum that satisfied the DSM-IV for nicotine dependence?

A. No, no, that got us to -- it's 17 percent of the daily smokers.

Q. Okay.

A. And the daily smokers represent, I believe,

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it's 46 percent of the general population.

Q. So in a -- if you could apply to it to the general population, what you're saying is if these results statistically could be applied across the board to all smokers, daily smokers --

A. Yes.

Q. -- 17 percent everything else being equal and if it was a fair survey?

A. Right.

Q. And correct demographically?

A. Right.

Q. 17 percent of daily smokers would experience withdrawal?

A. Correct.

Q. Now, is the DSM-IV nicotine withdrawal criteria something you agree with?

A. Do I agree with it?

Q. Do you have the same problems with the withdrawal criteria that you have with the dependence criteria?

A. Well, I have problems characterizing it as a withdrawal syndrome, but as long as we recognize that that's what a committee has proposed as the punitive withdrawal syndrome for nicotine dependence, what this tells me that, in fact, that is not a

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consistent syndrome, but it occurs only in 17 percent.

Q. I understand that.

A. But I do -- I will accept that as a reasonable description based on the symptoms that people report when they stop cigarette smoking. It represents the kinds of symptoms that have been reported even though they're not very consistent. I have not yet done a detailed analysis to see whether the pattern of correlations among the individual symptoms really has the psychometric properties that would allow you to say that this is a distinct syndrome. And I have asked similar questions about people stopping other habits and making other lifestyle choices in order to evaluate the specificity of these complaints for stopping smoking as opposed to stopping exercise or changing diet.

Q. Now, have you seen other studies whereby the rate of withdrawal symptoms was measured as a ratio of all smokers who attempted to quit?

A. Yeah. That is the only way you can meaningfully ask the question, I believe, is you have to have people to have used cigarettes regularly and then to have stopped.

Q. Okay. Have you seen --

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A. So that's the way it's done.

Q. You've seen other studies?

A. Yes.

Q. And what percentages have you seen attached to those studies?

A. I haven't actually seen a epidemiologically based study like this. I know that there are some that exist in twin studies, but I have not seen reported data of the epidemiology of this kind. That's one of the reasons why I wanted to do it. A lot of the reports are based on treatment samples and are not -- don't -- can't be generalized of the general population, so I just wasn't sure exactly what the percentages were.

Q. Well, when the American Psychiatric Association put together its criteria for nicotine dependence do you know if they looked at whether or not withdrawal was a pretty consistent pattern of people who had attempted nicotine cessation?

A. They did not do a study comparable to this. They looked at cases from clinical samples, treatment samples. They did not do an epidemiological study.

Q. And does not the World Health Organization list withdrawal as one of the criteria used to evaluate whether or not somebody is nicotine

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dependent?

A. Yes.

Q. Correct?

A. Yes.

Q. Do you know what research was done before that organization determined that the existence or not existence of withdrawal symptoms was relevant to the issue of whether or not nicotine was dependence producing?

A. A few years ago I did a literature review to try to identify all articles that validated the DSM or the ICD criteria, and we came up with really no well-done general population studies. We came up with a few treatment studies, and so this is -- this is one of the problems that those criteria had when they were first proposed is they really did not have a good factual basis.

Q. Do you know what they relied upon in establishing these criteria?

A. There have been -- there have been treatment studies where people describe the symptoms that people reported when they stopped smoking, and so it was based on those kinds of selected treatment samples where you -- where you can say these symptoms were reported, but you don't have any control about

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what selection biases may have gone into how the person happened to get into that treatment sample.

Q. Now, the World Health Organization does list nicotine dependence as a disorder; correct?

A. Yes.

Q. And it does list as one of the factors in arriving at that conclusion that there is withdrawal related to the use of nicotine on cessation of the use of nicotine; correct?

A. Yes.

Q. And that's also true with respect to the American Psychiatric Association?

A. Yes.

Q. Is it also true with respect to the National Institute of Drug Abuse?

A. NIDA also uses the same criteria. Remember you're -- that the reason that those criteria are there is not that a lot of work has been done with nicotine to document them, but that they're using general sets of criteria for substantial dependence that are largely founded on concepts that come from studies of alcoholics and heroin dependent people.

Q. We can debate and obviously you have a difference of opinion than virtually every organization in the world on the topic, but we can

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debate that another day. What I'm interested in just running through the list of organizations that we can all agree sitting in this room whether it's good, bad, or indifferent they list nicotine dependence as a disorder and they list withdrawal symptoms as their criteria for determining whether or not somebody is nicotine dependent; okay?

A. I agree.

Q. National Institute of Drug Abuse does; correct?

A. Yes.

Q. World Health Organization?

A. Yes.

Q. American Psychiatric Association?

A. Yes.

Q. American Medical Association?

A. Um -- all of these organizations would endorse these criteria just by the fact that they are part of the DSM-IV. So you don't really have to list the individual organizations. They all have to use the DSM-IV, the ICD criteria. Unless they come up with their own criteria and none have, those are going to be by de facto. They're criteria of all those organizations you might list.

Q. Your employer has a smoking cessation

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program; does it not?

A. Yes.

Q. What's it called?

A. Actually, they just put up posters that say "smoking cessation." I don't think it has a name beyond that.

Q. Does your employer endorse the view that nicotine dependence is a disorder?

A. I don't know that they've really taken a formal position on that.

Q. Did they follow the DSM-IV insofar as nicotine is concerned in their cessation program?

A. I don't believe they require anyone to receive a diagnosis. I think that the idea is that we are a no smoking building and so they want to offer this as a service to employees who want to stop smoking so for their convenience.

Q. Okay. I know --

A. So it doesn't require a diagnosis.

Q. Don't this have a cessation program actually employees can sign up for and participate in?

A. As a convenience.

Q. Well --

A. Doesn't require a medical diagnosis or a

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medical referral. If you want to go, you can go. If you don't want to go, you don't have to go.

Q. What is the program that your employer offers to help people stop smoking?

A. It's a fairly standard cognitive behavioral smoking cessation type program that provides education and motivational talk and group support.

Q. Are nicotine replacement prescriptions part of that program if the patient so desires?

A. They're available not required but available.

Q. Both patches and gum?

A. I'm sure they are. I don't know that for a specific fact, but I know that, you know, you can ask any physician you want. You can get them over the counter now.

Q. Have you participated in those programs?

A. No.

Q. What department or group within the hospital organizes those programs?

A. That's done on a contract basis by the hospital administration with people in the community, psychologists in private practice provide the supervision and direction.

Q. And you've never been asked to assist or

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provide any consultation with respect to that program?

A. I have had some consultation about it.

Q. What for?

A. Discussion about assessment procedures and that was the limit of it.

Q. Who developed the assessment procedures for the program?

A. At this point, they really are not using consistent assessment procedures and that's the only thing that I discussed with them is whether they -- whether they should or not.

Q. Now, the people that enter that program, do they have to pass a certain test before they're allowed to enter?

A. No.

Q. They have to smoke a certain amount of cigarettes a day before they enter?

A. No.

Q. They have to smoke for a certain amount of time?

A. Anyone who wants to go, can go. If they don't want to go, they don't have to go. It's completely open ended.

Q. Who did you have to get approve from at the

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hospital before you were allowed to testify in those matters?

A. Nobody.

Q. Has your testimony in these matters ever been the subject of discussion, debate, etc., at the hospital?

A. No. But that doesn't mean that some people might not discuss it amongst themselves, but there's never been any official discussion.

Q. Now, the use of the phrase -- I mean there's nicotine dependence. Is there a catch all substance dependence in the DSM-IV? Is there a title category above all types of chemicals?

A. Right; it's substance dependence.

Q. Is it fair to say that the criteria for determining whether somebody is nicotine dependent is similar to whether or not they're dependent on other substances?

MR. NIMS: Objection.

THE WITNESS: Would you repeat the question?

Q. (By Mr. Maistros) that's very poorly worded. Is there a criteria for substance dependence independent of nicotine dependence?

A. As I've been saying repeatedly, there's one

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general set of criteria for all substance dependence.

Q. Right.

A. And then the effort is made then to have every substance then follow that same outline.

Q. But there are, are there not, specific criteria for nicotine?

A. No, actually, there's one set of criteria for all substances. There's a discussion in the text of DSM-IV that points out the difficulties of fitting some of the criteria to nicotine, and there are suggestions as to what might count as something that is characteristic of nicotine or tobacco use that would be similar to the general content. For example, change smoking is used as an indicator of people going out of their way to obtain the substance.

Q. But when you, for example, list on your insurance claim forms or bill the Government for services you perform, in those rare occasions where you might diagnose somebody with nicotine dependence, would you list a substance abuse code word or would you list a specific nicotine dependence code?

MR. NIMS: Objection; I believe he's already testified he can't recall ever having that on a claim form.

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Q. (By Mr. Maistros) Well, I said if you would, what would you list?

A. There are specific codes for individual substances and there's a specific code for nicotine that's different from the others.

Q. So the DSM-IV insofar as nicotine is concerned, is your problem that nicotine is attempted to be placed as a dependence-producing substance or that the specific criteria for nicotine dependence are not very helpful?

A. I'm sorry, would you repeat the question?

Q. The problem you have been talking about today and in your other depositions that you have with nicotine dependence insofar as DSM-IV is concerned, is it related specifically to the criteria for substance dependence or nicotine dependence?

MR. NIMS: Objection.

THE WITNESS: Nicotine.

MR. MAISTROS: Do you want to take a break?

(A short break was taken.)

(A certain document was marked Exhibit Number 5 for identification by the Reporter.)

Q. (By Mr. Maistros) I'm going to mark as

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Exhibit 5 the National Health Study II Lifestyle and Health questionnaire you've talked about in some detail that you took out of the Hoskins file. I think we're only talking about pages 22 and 23. And you identified if you just asked the DSM-IV questions, you could eliminate or get it down to 10 questions; correct?

A. Yes.

Q. Do you know which 10 those are?

A. Yes.

Q. Just by number?

A. It would be 13 through 23 except for 14.

Q. You wouldn't use that word "addiction"?

A. Correct. That was just added in order to see what people mean when they say that get some general sense of what its prevalence was.

Q. Now, do I understand also that by these 24 questions you have questions built in here to determine whether or not at least the respondents fit the criteria of withdrawal symptoms related to nicotine?

A. Yes.

Q. And are those withdrawal symptoms out of a specific test?

A. DSM-IV.

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Q. And they are withdrawal criteria for nicotine?

A. Yes.

Q. Why did you --

A. And those are specific to nicotine.

Q. And why did you select DSM-IV4 in determining if your respondents experienced withdrawal symptoms?

A. Because those are the DSM criteria that we use officially in the United States.

Q. And they are recognized are they not in the scientific community as being reliable?

MR. NIMS: Objection.

THE WITNESS: Well, no, I wouldn't go that far.

Q. (By Mr. Maistros) Are they recognized by the American Psychiatric Association?

A. For clinical use, but that doesn't necessarily mean that it's psychometrically or scientifically reliable and valid.

Q. Did you select the best and most appropriate criteria that you could when you prepared this questionnaire?

A. Yes.

Q. So at least in the summer of '95 -- was

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that when you did this?

A. Yes.

Q. At least in the summer of '95, it was your opinion that the DSM-IV offered you the best criteria for evaluating whether or not somebody fit the definition of having withdrawal symptoms related to nicotine?

A. Yes.

Q. And whether or not they're nicotine dependent?

A. Yes.

MR. NIMS: Objection.

Q. (By Mr. Maistros) Now, which of these questions tell you whether or not somebody experienced withdrawal symptoms related to nicotine cessation?

A. Question 12 and the ones that follow it. When I said yes a moment ago, it's subject to the same qualifiers that we had before when you asked me about if someone was nicotine dependent. I take that to mean satisfying criteria and we've already discussed several times that I think there are some limitations of those criteria.

Q. But if somebody forced you to select criteria and if you want to do a scientific survey

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such as you did in 1995, out of the universe of criteria you would select the DSM-IV's?

A. Well, but remember I selected this in order to try to evaluate the adequacy of those criteria. I'm still in the process of doing that evaluation. Those are the criteria that I wanted to evaluate. I wouldn't take them as a standard and saying that they're -- it's not so much that they're the best. I wanted to characterize the official criteria and to see just how well they work and what the interrelationships are between alternative criteria.

Q. When are in your findings going to be published?

A. I'm actively engaged in analysis of these now, and I think it will probably take another -- I would think over the next year that we'll have publications prepared from this.

Q. Now, how are you going to test whether or not their responses met your definition, your definition of adequate criteria?

A. There are a number of things that I can do here. One is to simply to describe the patterns of agreement or non-agreement between alternative criteria like the Fagerstrom and the DSM. Another is to evaluate the patterns of correlation among the

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criteria. In other words, if this is really a syndrome, do those symptoms correlate with one another, so that the scale has what's called internal consistency.

Q. Were you actually going to interview the respondents?

A. I don't plan to. And then the other thing that this questionnaire is designed to do is to help me evaluate the specificity of these kinds of patterns of response by comparing the difficulties people have or don't have with cigarette smoking and those that they have when they start and stop exercising, change their diet, change their stress, and so on.

Q. What was the overall larger purpose of this study?

A. Overall purpose was largely twofold. One is normative analysis of personality structure and the relationship of personality to a wide variety of lifestyle choices, including exercise, diet, stress management, cigarette smoking, alcohol use, and to evaluate patterns of decision making with regard to lifestyle choices like those.

Q. You've done similar surveys in the past; have you not?

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A. Yes.

Q. Many times; right?

A. Yes.

Q. How many times have you included a section on cigarette smoking?

A. Let's see, this is the second time that I included a section on cigarette smoking and -- yeah.

Q. Is this more -- and the first time was in your paper that you've identified as Exhibit 4?

A. Correct, the year before.

Q. Are the questions in this questionnaire, Exhibit 5, more extensive than they were when you prepared Exhibit 4?

A. Yes, they are.

Q. Insofar as cigarette smoking is concerned?

A. That's correct.

Q. Why did you ask the question of the respondents, do you feel you were ever addicted to smoking cigarettes?

A. The word "addicted" has come to be used so broadly in our society that it can be applied to almost any behavior that's repetitive, including gambling and eating chocolates, and so on. So I wanted to see what characteristics people have in terms of Fagerstrom and DSM criteria when they say

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Source: https://www.industrydocuments.ucsf.edu/docs/vfxl0001

I'm addicted to smoking. That would give me more of a feel for how is that word being used with regard to -- with reference to cigarette smoking because it can mean so many different things.

Q. The overall goal is it not is twofold is one, is to determine how many people responded that fit the dependence criteria?

A. Yes.

Q. And two, is the withdrawal criteria?

A. Yes.

Q. And you believe that whether or not somebody responded that they thought they were addicted would shed light on that?

A. I honestly just didn't know what people meant when they said it, and so this was a way to ask a broad set of questions and then just see okay what does it mean.

Q. Did the --

A. I'm not sure.

Q. Did the percentage of smokers that fit the DSM-IV dependence criteria -- what percentage answered that question yes, I feel I've been addicted to cigarette smoke? That's not how it's phrased exactly, but it's question 14.

A. Yeah. To the best of my recollection

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80 percent of people who were daily smokers said that they had thought they were ever addicted whereas 50 percent of people actually meet the DSM -- 50 percent of those meet the DSM criteria for dependence. So the word "ever addicted" or the phrase "ever addicted" is being used much more liberally.

Q. But did 100 percent of the people who met the DSM say they felt they were addicted to smoking cigarettes?

A. I actually don't think I've made that exact cross calculation. My impression is that there's a strong overlap, but I'm not actually sure. It's something I can do in the future, I haven't done it yet.

Q. Did you give consideration to asking if these people that they thought that cigarette smoking was a habit?

A. Well, what I did was to choose -- it wouldn't have worked in this interview because -- in this questionnaire -- because I had limited it to those people who were already daily smokers and so being a daily smoker is almost by definition a habit and daily, in fact, that is the term is sometimes used "habitual smoker" or "regular smoker" that's

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often used interchangeably with daily smoker. So given the way I set the interview up, it wouldn't have made sense to ask that question.

Q. Did you give consideration to asking these daily smokers if they were dependent upon their cigarettes?

A. Actually, I -- it just didn't occur to me. We were trying to, you know, have a limited number -- a limited amount of time and those questions just didn't jump to my mind when I was putting the questionnaire together.

Q. Now, the questions 13 through 23 are those the ones that if you limited yourself to DSM-IV, that you could ask and determine if they met those nicotine dependence criteria?

A. Well, those questions do correspond to the DSM criteria. There is no official guidance as to how you would phrase questions like that, but that's a conscientious effort to do so.

Q. And how many of these questions would a respondent have to answer yes to fit the DSM-IV nicotine dependence criteria?

A. Let's see, if I can look at it. It actually isn't that simple. I'd actually have to sit down with the criteria and work out the code. The

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reason is that among the seven criteria for dependence you can satisfy some of them two ways and so there are a couple of -- there are multiple questions that could fit. You could have both -- you could have two right but only get one count toward the criteria, so I'd have to sit down and work it out on paper and pencil, so I can't give you a certain number off the top of my head.

Q. If I answered yes to the question, have you ever used nicotine gum or skin patches to stop smoking?

A. Well, you know the criteria for DSM is that you have to have three of seven, I believe, features in addition to clinically significant impairment overall.

Q. Are there any of these ten, 11 questions actually, that you could check off as saying pretty much track the DSM-IV criteria?

A. No.

Q. But you based upon them on the DSM-IV criteria?

A. Yes.

Q. Is that because people respond -- lay people would better understand the way you phrase questions as opposed to how they're phrased in the

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DSM-IV?

A. Well, the DSM-IV doesn't actually give a clinician questions, it gives a behavior and then it's left to the clinician to figure out to ask the question to elicit a meaningful answer. And if you're making a questionnaire up, you have to figure out a way that the question will be clear to a people with a wide range of reading abilities and backgrounds and have it be answerable in a simple, yes, no format, so it's a bit of an art to do this.

Q. Did your decision to limit the application of these criteria to daily smokers -- is that something generally recognized that if you're not at least a daily smoker, you don't ever have to get to the DSM-IV's?

A. I don't think that the concept of dependence can be applied very well to people who aren't at least daily smokers. That doesn't mean that everyone who's a daily smoker is dependent and it doesn't mean that you couldn't -- I could imagine that people could begin to talk about or think about dependent behavior in people who aren't -- don't do something daily. For example, gamblers are sometimes said to be addicted to gambling or to sex, or people are sometimes said to be addicted to sex. Now, that

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doesn't mean that to be dependent on gambling or sex or chocolates, you have to do that everyday. But I'd say it was a reasonable decision, but not one that's beyond all question.

Q. Now, the 50 percent or so that met the DSM-IV criteria for nicotine dependence, how would you describe those people? I mean once they satisfied that criteria, assuming you espouse the view that DSM-IV has some accuracy or validity; would it be fair to describe those people as meeting the American Psychiatric's Association's definition of nicotine dependent people minimally?

MR. NIMS: Objection.

THE WITNESS: To meet the criteria you would at least have to do that and then as I said there are some other things that require judgment about over overall clinical impairment significance that I'm not able to do is in a questionnaire survey like this. So I would take this as a proxy for those criteria reasonable to do in a questionnaire survey of the general population like this where there's no reason for bias but not necessarily usable as it is in a clinical population or a litigant population.

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http://legacy.library.ucsf.edu/tid/pkp97a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/ytxl0002

Q. What is the purpose of question 24, since you started smoking daily what is the longest time you've gone without smoking anything?

A. Can I look at it again just to -- oh, okay. I wanted to get information about something that is unclear in the literature, which is the frequency of abstinence in people who are current smokers or former smokers, and to see how that's related to other dependence-related behaviors to see whether we can predict -- whether there was anything that would predict duration of abstinence.

Q. Now, somewhere in your testimony whether it was today or in another deposition I believe you expressed the view that you do not believe smokers develop a tolerance to cigarettes?

A. What I said was that people smoke cigarettes in -- my statement I said that people often smoke the same number of cigarettes for years without reduction in their pleasure from that.

Q. And what questionnaires have you done to establish that fact?

A. Actually, that is based on clinical interviews with a large number of patients and friends. It's the common report that people often will go many years smoking the same number of packs

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of cigarettes or numbers of cigarettes per day and indicate that they enjoy it. That is a very consistent history.

Q. And in that course of that clinical research that you did or clinical answers and questions sessions, whatever you want to call it, did you ask these people for how many years they smoked the same packs versus when they started to smoke the same packs versus the type of cigarettes they smoked?

A. Yes.

Q. Do you have any literature that documents those answers?

A. There are -- I've certainly read a number of studies I haven't seen complicated curves that demonstrate what the rate of progression to the plateau is but it's my impression from the bits and pieces that I can put together is that people vary some but depending on their lifestyle situation, they often get to a plateau that then remains stable as long as there are no other major changes in their lifestyle. That's an impression.

Q. Now, the rate of progression to the plateau have you done any studies to determine what that is?

A. No.

Q. Is that a scientific term "rate of

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http://legacy.library.ucsf.edu/tid/ele07e00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/yxl0001

progression"?

A. Well, yes.

Q. Does that like you smoke your first cigarette when you're 12 and then by the time you're 17 you're smoking a pack a day?

A. Right. The reason it's difficult, I guess, is the issues are often influenced by availability and depending on the age that people start, there may be, you know, the amount of money that you have, your access to it, your age, and so on can serve as deterrents and so it's I think difficult to interpret the existing data because those variables can't be precisely quantified and controlled.

Q. Have you seen any research where people when they begin to smoke smoke less cigarettes per day than they do after they reach the plateau?

A. Do people increase you mean from what they smoke on their first day to what they smoke --

Q. Yes.

A. -- on the last. Well, yes, of course, there's an increase and the reports are that this is largely due to some rapid development of tolerance to the adverse effects of smoking but that once people become tolerant to the adverse effects, that actually there's then a very stable period where people go for

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Source: https://www.industrydocuments.ucsf.edu/docs/yjx0001

many years in adulthood smoking the same level of -- same number of cigarettes per day.

Q. Have you seen similar research with respect to alcoholics?

A. Yes.

Q. Have you seen similar research with respect to heroin?

A. Well, some.

Q. When I say similar research, that's where you begin at a certain level, increase, and then plateau?

A. Uh-huh.

Q. You've seen that for alcohol?

A. Yes.

Q. You've seen some for heroin. Have you seen it for cocaine?

A. Yes. Now, please understand that with my saying yes to that doesn't mean that the patterns are the same for those substances as for nicotine. In fact, the evidence is quite the contrary that for those other substances to get the same stimulation or anxiety reduction from those substances that there is a pattern of progressive increase indicating tolerance to the pleasurable effects of those substances.

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Source: https://www.industrydocuments.ucsf.edu/docs/yjx10001

Q. But those substances I listed there's also research which indicates is there not that a certain plateau is achieved at some point in time where there is minimal increase in intake?

A. No, people actually, quite the contrary, that's the problem with things like cocaine is that people just keep increasing the dose until they literally pass out or die from the effects.

Q. How about alcohol?

A. And heroin also, alcohol also.

Q. Is there tolerance developed with respect to cocaine?

A. Yes, definitely.

Q. Is there tolerance developed with respect to alcohol?

A. Yes.

Q. And is there tolerance developed with to heroin?

A. Yes.

Q. And is there tolerance developed with respect to nicotine, whether it's at a different level or not? I'm not interested right now in the level, I'm talking about tolerance.

A. Well, there are reports that there is some -- there may be some development of tolerance to

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the pleasurable effects of nicotine and that you see patterns of dosage increase initially. The difficulty is that it seems that that could also be explained by the development of tolerance to the adverse effects of nicotine that may be -- that I think is hard to unconfound from the development of tolerance. What I think you can say what's unique about cigarettes is that with heroin and alcohol and cocaine, adults continue to have to increase the dose if they use it on a daily basis in order to get the same pharmacological effect, whereas with nicotine adults go for decades smoking exactly the same number of cigarettes, not having to increase it, and still report the same enjoyment from daily smoking. That's quite unique among substances.

Q. What tolerance studies have you done on nicotine?

A. That is limited to my reading of the literature and also asking people whether they have to -- whether they've increased the number of cigarettes that they're smoking over the years and whether they're still enjoying it as much as they used to when they first started smoking at that level. I've often asked that question of my patients and friends that I know and consistently find that

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unlike other substances they report that they go for long periods of time and still enjoy it. That's quite distinct from all the reports that I've gotten asking similar questions about other chemicals, other substances.

Q. Do you know what research Reynolds or any other defendant has done on tolerance to nicotine?

A. No.

MR. NIMS: Objection; lack of foundation.

Q. (By Mr. Maistros) When you elected to put in a section on cigarette smoking in your 1995 survey, did you run that by Jones Day?

A. No, I didn't.

Q. Was your interest in cigarette smoking peaked in any manner by your involvement in testifying on behalf of the tobacco defendants?

A. Well, I think that the first issue for me was that I wanted to measure lifestyle choice, and cigarette smoking and alcohol consumption are both regular parts of that. Second, and that's been a standard epidemiological consideration for a long time in the area of lifestyle choice, second, in connection with my work on the etiology of alcoholism, there's been more and more interest in

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the overlap between the use of cigarettes and alcohol. And so that has been a major scientific factor where -- so that peaked my -- that's what really peaked my interest. Then I couldn't help but be interested in getting more detail about some of these relationships from the questions that arise in this kind of testimony. So that is a factor. I would say it's probably the third in a list of factors.

Q. When you use "lifestyle choices" does that have scientific meaning?

A. Yes, most states do periodic epidemiogical surveys in which they look at things that are called lifestyle choice as a group and those usually include diet, exercise, alcohol consumption, cigarette smoking, and stress management techniques. Those are the areas that I included in this survey because those are the standard epidemiological targets.

Q. Do you have any association with the State of Missouri?

A. I used to be one of the commissioners for mental health in Missouri. I don't have a formal relationship to the State at this point. When I designed this survey, I talked to people in our state and in other states to get copies of forms that they

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Source: https://www.industrydocuments.ucsf.edu/docs/vtxl0001

used in doing epidemiological surveys, but it was -- that was just a matter of courtesy among different scientists and epidemiologists.

Q. And what years were you a commissioner of mental health?

A. I think it was about 1990 to '94, but let me just double-check. 1990 to '94.

Q. Was that an appointed position?

A. Yes.

Q. By whom?

A. Governor.

Q. Do you know if the State of Missouri is suing the tobacco companies?

A. Gee, I don't know. I don't think so, but I haven't heard anything about it one way or the other.

Q. When you were the commissioner of mental health for the State of Missouri, how many commissioners were there?

A. Seven.

Q. Did you meet regularly?

A. Yes, monthly.

Q. Did you develop policies for the State?

A. Yes.

Q. And during that four-year period did you develop any policies related to smoking?

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A. No.

Q. How about substance abuse?

A. Substance abuse is one of the sections of the Department of Mental Health, and we did increase our efforts to reduce the availability and sale of alcohol to minors, which has been a major problem in our state. The laws have been there, but it's been very difficult to enforce.

Q. And none of your work with the mental health commission -- is that what it was or a department?

A. Well, the commission supervisors or monitors the department.

Q. Did the commission or department utilize the DSM-IV's with respect to any work it was doing?

A. Yes.

Q. And in what capacity?

A. Well, the State Department of Mental Health has to use the officially endorsed diagnostic criteria nomenclature just like hospitals. And so actually as the psychiatrist on the commission, that was part of my responsibility as to advise and consult on those kinds of procedures.

Q. And that would include in 1990 to 1994 the use of the DSM-IV on nicotine dependence?

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A. Well, at that time, it would have used DSM-III-R, but we would have used the, at that time, current DSM criteria for substance dependence in general. Generally speaking, though, I don't know that the department actually sponsored smoking cessation programs. I don't know for a fact that it didn't, but I know that most of our concern was with other drugs, such as principally alcohol and heroin and cocaine, marijuana to a lesser extent.

Q. Nicotine is a drug; correct?

A. Nicotine is certainly a chemical and it's a substance. Now the word "drug" has a number of meanings as a matter of legal statute. And so to ask me the question is it a drug that's one of those words you wanted me to call to your attention if a word had multiple meanings and it would depend.

Q. Does the FDA consider nicotine a drug?

A. I believe that was the issue, one of the issues that Dr. Kessler, had brought before the FDA is whether it should have the authority to regulate tobacco sales as if it were a drug under the FDA act, FDA standing for Food and Drug Administration.

Q. Do you know if the FDA considers nicotine a drug?

A. Well, I'm actually not an expert on

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Source: https://www.industrydocuments.ucsf.edu/docs/ytxl0001

actually where that stands at this moment. I know that that has been a point of contention. At the present time, it's my belief that the FDA is not regulating the sale of cigarettes in the way that it does the sale of pharmaceuticals that are prescribed by doctors, so there seems to be at least currently a difference in the way in its authority with respect to various substances. So I think that tobacco still seems to enjoy a somewhat distinct status from what the FDA often considers a drug. I can't speak more authoritatively than that.

Q. Do you know what a controlled substance is?

A. Yes.

Q. Is nicotine a controlled substance?

A. I don't believe so. You can get it without a prescription from a doctor, and it's not on a list of controlled substances.

Q. Do you know what is scheduled controlled substance is?

A. Well, that's actually what I was referring to about the scheduled drugs. Scheduled drugs of abuse are things that are considered to be dependence-producing like narcotics and analgesics and sedatives.

Q. And it's your testimony nicotine is not a

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http://legacy.library.ucsf.edu/tid/elo07e00/pdf Source: https://www.industrydocuments.ucsf.edu/docs/yfxl0001

scheduled drug?

A. That's correct. I'm not aware of it being on -- I'm not aware of a prescription from a physician being required to obtain a pack of cigarettes, and I believe that to get a scheduled drug, you have to have a prescription from a physician --

Q. Well, nicotine --

A. -- who's authorized to make such a prescription.

Q. Nicotine to the best of your knowledge, is the chemical or agent in tobacco that has the largest effect on the central nervous system?

MR. NIMS: Objection.

THE WITNESS: Well, I have said in other depositions before that there is evidence that the effects of cigarette smoking are more complex than the effects of nicotine alone, and that there are multiple substances in cigarettes that contribute to the taste and the enjoyment and the aroma that I believe are important in people's decision to smoke or not to smoke. And so I recognize that there are -- that nicotine is something in cigarettes that makes a

Source: https://www.industrydocuments.ucsf.edu/docs/ytxl0001

substantial contribution to the psychoactive effects of smoking, but I don't -- I wouldn't go so far as to say that you can understand why people smoke from simply understanding the pharmacological effects of nicotine.

MR. MAISTROS: Read my question back.

(The requested portion of the record was read by the Reporter.)

MR. NIMS: Objection.

Q. (By Mr. Maistros) Can you answer that question? Not why people smoke, not the psychological reasons.

A. Largest effect on the central nervous system.

Q. What chemical in tobacco has the greatest effect on the central nervous system?

A. I'm not sure I know the answer to that question.

Q. Do you know when Reynolds knew the answer to that question?

A. I'm not sure anybody knows the answer to that question. I think you might get a lot of opinions, but I'm not sure anyone really knows the

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf Source: https://www.industrydocumentslibrary.ucsf.edu/docs/xj0000

answer to that question. Part of the reason I think that is that I don't think you can simplify that question to, in that neat way, to just what are the CNS effects of alcohol because remember the effects on the central nervous system include things like the taste, the aroma, the enjoyment, and so there really is a very strong relationship between why people smoke and CNS effects. At least that's the presumption that in Hoskins, Henningfield and Fiore make the assertion that nicotine is the thing in cigarette smoke, in cigarette and tobacco, that is responsible for the dependence-producing effects of cigarettes smoking. And in my statement in response to that I raised questions that that's the case simply because of the observation that nicotine replacement does not, in fact, predict cessation behavior, and if it doesn't predict cessation behavior with regard to smoking, then it's hard to, if at all, it's hard to make the case then that it's nicotine that accounts for the principle central nervous system effect. I don't think you can have your cake and eat it, too. And like I said, to make the claim that nicotine is what does it all and then to also publish findings that nicotine levels do not predict whether someone is able to quit smoking or

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not, doesn't add up, something is missing, and I don't think we know what that is.

Q. Okay. A portion of your answer to or a portion of your statement really wasn't an answer to my question, but a portion of your statement you just made was nicotine replacement doesn't predict cessation behaviors?

A. Yes.

Q. Now, is that something that you found to be true only with respect to nicotine or is similar results found with respect to methadone, for example? What is methadone a replacement for?

A. Methadone is a long-acting opiate and it's used as a replacement or substitute for opiates in general.

Q. Is that a good predictor of --

A. Actually, the best outcome results in heroin addicts or opium addicts is methadone replacement.

Q. I'm not talking about results. I'm saying -- talking about prediction of cessation behavior. What's the rate that you can predict cessation behavior by methadone replacement?

A. Actually, if you -- if you give someone -- if someone stops smoking and you give them a patch,

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Source: https://www.industrydocuments.ucsf.edu/docs/ytxl0001

you're replacing nicotine, that's the logic. With methadone you give people -- you ask them to stop using heroin or other opiates by giving them methadone and if you maintain them on methadone, then their use of other drugs is, in fact, substantially reduced. And so methadone substitution is, in fact, a good predictor of people stopping use of other opiates.

Q. Do you know what that percentage is?

A. As a percentage that will also -- that is substantially improved but the proportion who actually stick with the methadone program and stop other problem behaviors is also a function of other substances that they might have been abusing, whether they've got a job, and other kind of social factors. So I can't give you a simple percentage but, in fact, in multi-model programs that provide where you've got good social supports, combined with methadone, you actually find that the majority of the people put on methadone do well.

Q. Do you believe that methadone alone can be used to treat heroin addicts?

A. Methadone alone makes a big contribution but to optimize the results it's recognized that you need to do other things as well.

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Source: https://www.industrydocuments.ucsf.edu/docs/vjxl0001

Q. Such as counseling?
A. There are programs --
Q. Such as counseling?
A. Such as counseling. There is a lot of variation in the quality of methadone substitution programs and some actually do involve little more than giving people methadone prescriptions or access to methadone. Those don't do as well, but they actually do lead to improvement.
Q. Now, when you say that nicotine replacement doesn't predict cessation behavior, you're not suggesting are you that nicotine replacement doesn't have a role insofar as nicotine withdrawal or nicotine cessation is concerned?
A. No, there --
MR. NIMS: Objection.
Q. (By Mr. Maistros) I mean that's not what Fiore said; did he?
A. No, what -- two things, one is that the nicotine level before cessation doesn't predict outcome. Second, giving replacement does not stop the urge to smoke and the increase in the improvement in the people who do or don't get nicotine replacement is not very substantial. So that the real determinant seems to be people's psychological

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expectations or self-directedness in overcoming, you know, achieving goals, what is it they really want to do. So, as I said earlier, nicotine replacement can have a role, a limited role I believe, in my opinion at least, if the person feels that it would be helpful to them. But most people don't, as I showed you, don't have withdrawal and so it's not really relevant to them.

Q. So I guess the only time you have prescribed the patch or gum is because people thought it would help them, you didn't make a determination it was medically necessary or required?

A. Correct.

Q. And that would include people you've prescribed on Medicaid and Medicare?

MR. MURPHY: Objection to the form of the question.

Q. (By Mr. Maistros) Have you ever read your Medicaid and Medicare contract and the representations you make when you sign a claim form to Medicaid and Medicare.

A. I'm was trying to think whether I've ever prescribed a patch to anyone on Medicaid or Medicare. I don't believe I have.

Q. What about your insurance claim forms?

Source: https://www.industrydocuments.ucsf.edu/docs/yjxl0001

Have you ever read those to see what representations you make when you approve prescriptions of such a substance?

A. You see, I don't think that prescribing, writing prescription to someone, involves a report to Medicare or Medicaid. I'm not charging for writing that prescription. Now, if someone has a discount in some formulary, then that's between them and their formulary or their insurance plan. I'm not involved in that transaction. When I write a prescription it's only because it's to the benefit of the patient and the benefits outweigh the risks. I'm not in any plans that would further curtail my choices.

Q. You have not done any -- personally done any research to determine the value or efficacy of nicotine replacement therapy?

A. No.

Q. And it's your understanding of -- was it Fiore's work that he has found that there's no correlation between nicotine replacement therapy and withdrawal success or cessation success? Doctor, do you want Fiore's?

A. No, I've got it here.

In two studies that he did the curves of people on active patches that contain nicotine and

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those that don't follow essentially the same relapse curve with no significant differences between the groups. So you would conclude that the nicotine patch does not have any substantial effect on achieving abstinence.

Q. What study is he referring to?

A. This is the study of Kenford, et al., in JAMA in 1994.

Q. And he's listed on there?

A. Yes, sir, he's the second author.

Q. And what report are you looking at?

A. I'm looking at it's most clearly seen because most of his abstract and text is about combination of variables, the overall effect can be looked on page 593 and you'll see curves for relapse people on active patch or on placebo patch, and you'll see these curves basically don't differ much from each other. Study one, there's a little but of a difference at the beginning, but doesn't reach significance and study two shows that there's essentially no difference between those on and off.

Q. Isn't the entire report you're reading, though, attempting to predict the success of nicotine withdrawal or cessation?

A. Yes, and it shows basically that you can't

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf

predict it with things like Fagerstrom or nicotine levels, and that's consistent with the fact that nicotine replacement also doesn't have that withdrawal effect.

Q. But the purpose of this report that you're reading from, which we might as well mark as Exhibit 6, which you took out of which file?

A. Hoskins.

(A certain document was marked Exhibit Number 6 for identification by the Reporter.)

Q. (By Mr. Maistros) Is it fair to characterize the purpose of the report predicting cessation as an effort to attempt to quantify or analyze what factors you could look at to predict whether or not somebody will be successful if they want to attempt to stop smoking?

A. Yes.

Q. The purpose of the report was not to analyze the efficacy or value of patches; was it?

A. Well, I think it is. In fact, it's subtitle is "Who Will Quit With and Without Nicotine Patch" and so one of things that you get out of this is both a measurement of the pre -- of the nicotine before a person stops and then the effect of nicotine

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Source: https://www.industrydocuments.ucsf.edu/docs/vtxl0001

replacement on outcome. And what it shows is that nicotine replacement doesn't make a difference and the pre-cessation nicotine or cotinine level doesn't make a difference and furthermore, the measures of the Fagerstrom criteria that are proposed as a class definition in Hoskins also don't predict it.

And what is found to make a difference is a psychological expectation about outcome. In other words, what is the person's commitment and desire? What do they want to accomplish?

Q. Now, in your treatment of -- you've treated heroin addicts; right?

A. Yes, sir.

Q. In your treatment of heroin addicts what do you find to be more determinant of success in cessations, psychological expectations or replacement therapy? Or if there's something else like genetics you want to mention, you can mention that.

A. In heroin addicts, I think there are two things that are really very predictive. One is the overall level of personality disorder, which can be measured by lack of self-direction. In other words, their lack of self-control and a similar variable, self-efficacy, is also emphasized in the nicotine or tobacco literature. A second thing, though, that is

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a substantial predictor is methadone replacement.

Q. When you just said nicotine or tobacco literature, did you mean heroin or did you mean nicotine?

A. Well, I didn't --

Q. I'm sorry to interrupt you.

A. I was trying to make a parallel to the fact that self-efficacy or self-directedness is also a predictor of how well someone does in smoking cessation. I'm not sure exactly what I -- maybe I should start over.

Q. Let's start over with the question so we don't have to figure out what we're starting over on. I asked -- started out with asking the proposition if you had to rank them insofar as heroin dependence is concerned between psychological expectation and replacement therapy could you rank those and would you rank one above the other in terms of importance for determining cessation success?

A. In cigarette smoking I would rank --

Q. No, just heroin.

A. Okay. With regard to heroin I would say that psychological factors like self-direction, goal directiveness, self-control are equally important, approximately equally important with a replacement

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strategy like methadone substitution.

Q. Okay.

A. I would say that they're both very important. I don't know the exact weight.

Q. So you wouldn't -- you wouldn't even fell comfortable putting one ahead of the other?

A. No, I think both are very important.

Q. How about -- and heroin is a dependence-producing substance?

A. Yes.

Q. How about cocaine? Those two factors could you rank them?

A. Well, there is no replacement strategy that I know of with cocaine. What the closest thing to a replacement strategy is the use of anti-depressants, sometimes with adjuncts that are of a non-euphoriant dopaminergic agonist.

Q. So would you place personality as the key factor in determining success from --

A. Personality --

Q. Cocaine cessation?

A. Personality and counseling alone with cocaine dependence I think is -- has limited success and so it is often a matter of finding a healthier non-dependence producing pharmacological strategy to

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help them cope with their emotional needs, so what I would do and what I have done with people with cocaine dependence is to get them on effective doses of anti-depressants and to combine that with what are called non-euphoriant dopaminergic agonist like Pentolin (ph).

Q. Well, the anti-depressants aren't a replacement for cocaine; are they? Do they really treat the withdraw effects?

A. No. Well, that's also one of the helps in doing that you get rapid relapse if you get depression. But in addition, sometimes the reason that people are using cocaine is that they're looking for -- they're looking to be happier and to be more positive and that's one of the things that you get from antidepressant, and anti-depressants are not dependence-producing so that there are strategies of pharmacological management that are a very important contribution to the treatment of cocaine dependence.

Q. But not as important as it is in the heroin setting?

A. It's hard to judge the relative importance of that. I would say that I have never ended up managing someone with cocaine dependence or heroin dependence where I wasn't also doing some sort of

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pharmacological manipulation.

Q. Now, in terms of alcohol, personality and replacement therapy, can you quantify or rank those?

A. I think the most effective factors are initial detoxification that allow people a safe withdrawal and then to combine pharmacological management with psychological management and that -- the studies about that are difficult. We're still in the phase of trying to work out exactly what are the optimal regiments for particular patients and at this time it's not possible to give a simple recipe, but my own practice and my own experience is that that combination of pharmacotherapy and psychotherapy as critical and that you can't -- I can't rank which is more important because I think you really do need both.

Q. What type of replacements are there for alcohol?

A. Well, two strategies that are used. I mean one is actually to use an antagonist of opiates, Naltrexone, for initial relapse prevention. That helps probably in the first few months and then after that, it's less important and in the longer run, I think use of anti-depressants, mood stabilizers, in my own practice is what I use to try to control and

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http://legacy.library.ucsf.edu/tid/ek07e00/pdf Source: https://www.industrydocuments.ucsf.edu/docs/wxl0001

help with the stabilization of mood states.

Q. No --

A. And then in addition there are, you know, cognitive and behavioral psychotherapy techniques that are very important.

Q. In your own practice have you counseled alcoholics; is that an okay term "alcoholic"?

A. Yes.

Q. Counseled alcoholics without the use of those quote "replacement" unquote their piece?

A. Sometimes, especially in the past, it was often advocated to by groups like AA to avoid all drugs, but I and many other people have increasingly found that that is sometimes not workable and I find that I get much better results by the combination of pharamacotherapy and psychotherapy.

Q. Do you use shock therapy in alcohol?

A. No, it's usually not necessary unless there's a severe, persistent, and concomitant depression. If by shock therapy, you mean electrical therapy --

Q. Yes.

A. That's what they're mostly doing.

Q. Are there occasions where you treat cocaine dependent people without using replacements?

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf

A. It would be -- it would be possible and I think within a standard of practice to try but most people with cocaine abuse will have associated emotional disturbances that will actually benefit from using medications with it.

Q. How about heroin have you counseled people on heroin withdrawal without using a replacement?

A. I have in the past but now I think that it's more effective to have combinations of pharmacotherapy and psychotherapy.

Q. Now, is it fair to characterize your 241 articles that you've written or thereabouts mostly dealing with the issue of why people abuse certain substances?

A. Yes.

Q. And is it also fair to say that as a general proposition, you believe that either genetics or personality goes a long way in determining why people abuse substances?

A. Yes.

Q. Is that the mainstream thought in terms of substance abuse generally that genetics and personality go along way towards explaining why people abuse substances?

A. I think so.

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Source: https://www.industrydocuments.ucsf.edu/docs/vtxl0001

Q. And that would be true regardless of the substance? I mean is there any substance that you can think of that you'd like to say I'm not sure that quite fits in my general belief?

A. No, I think that's true.

Q. And this is a view shared by psychiatrists; is it not?

A. Yes.

Q. Is it shared by biologists?

A. Biologists in general?

Q. Yes.

A. Well, they wouldn't be particularly informed or knowledgeable about this so a prudent biologist would probably defer to a specialist in that area, which would be a psychologist or psychiatrist.

Q. Now, who would know more about why people continue to abuse substances, a psychiatrist or a biologist?

A. Psychiatrist.

Q. Who would know more about how a certain substance interacts with the central nervous system, a psychiatrist or a biologist?

A. Oh, I see. I may have misunderstood how you were using the word.

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Source: https://www.industrydocuments.ucsf.edu/docs/ytxl0001

Q. That's a different question.

A. Okay. But that wouldn't be a simple -- that's not an answer that I can give you a simple -- that's not a question I can give you a simple answer to because a psychiatrist who could give you the most precise answer to those would be those who are neuropharmocologists or neurobiologists, and it's in that combination of expertise about both the clinical issues and the neurobiological issues that is important, and I think either a neurobiologist, who doesn't have the clinical background would be in a difficult position, and a psychiatrist, who doesn't know anything about the neurobiology or psychologist, say -- a social psychologist wouldn't be able to give you a very good answer.

Q. Now, we talked about nicotinic receptors and you mentioned one other type of receptor. I forget what was it? Cocaine or heroin? Was there a specific type of receptor?

A. I think I mentioned Dopamine.

Q. As a receptor?

A. Well, I talked about dopamine agonist, but let's see, was there another?

Q. I thought my notes -- anyway rather than guess, let me go through it. You know there's

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Source: https://www.industrydocuments.ucsf.edu/docs/yjxl0001

nicotinic receptors?

A. Yes.

Q. Are there heroin receptors?

A. There are receptors for opiates. We have naturally occurring opiate peptides like endorphins.

Q. Have you done research on those?

A. No.

Q. Are there receptors for cocaine?

A. Um --

Q. When I say receptors for cocaine I mean specific receptors that interact with cocaine?

A. Cocaine tends to stimulate dopamine receptors, so it's not specific for cocaine but that's the way that cocaine is acting.

Q. Are there receptors for alcohol?

A. No specific receptors for alcohol, but it does affect a wide number of receptor sites in the brain. It's just that it's not -- there's not a specific one for it. So it has both -- alcohol has both stimulant and sedative properties at differing doses and can affect both say dopamine and gab (ph) sites, as well as glutamate sites.

Q. Are there any drugs of abuse -- are there any dependence-producing drugs that you're aware of that have specific receptors such as nicotine? I

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mean you've mentioned opium receptors?

A. Well, opiates.

Q. Any others?

A. Well, the way drugs of abuse work is to alter neuro transmission or brain connections and that induces effects that are desirable by either stimulating pleasure centers or reducing anxiety and that is a common mechanism of action for drugs of abuse, as well as a common mechanism of action for a wide variety of habit formations.

Q. Including nicotine?

A. Nicotine and chocolate and, you know, eating fatty foods, anything that's pleasurable will change neurotransmission in the brain.

Q. Do you know what free nicotine is?

A. I believe that refers to nicotine that's circulating in plasma and it's not bound to a specific receptor. Unless -- I'm not sure -- actually, it could be something to do with being non-protein bound. That's a more general term, receptors being proteins.

Q. Have you ever been apprised of what research Reynolds has done on free nicotine versus bound nicotine?

MR. MURPHY: Objection to the form for

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lack of foundation.

THE WITNESS: No.

Q. (By Mr. Maistros) When nicotine enters the body where does it go? When it enters it through the mouth?

MR. NIMS: Objection. I'm really not an expert on this, but it enters into the bloodstream and via that route then is distributed throughout the body and would stimulate nicotinic receptors throughout the body.

Q. You know what its half life is --

A. No.

Q. -- in the human in the body? Do you know the rate at which nicotine is metabolized?

A. I couldn't give you specific figures for that.

Q. Do you know the speed with which nicotine reaches the receptors in the brain?

A. If taken up through the lungs, I believe it's very rapid, but I can't give you specific measures in seconds.

Q. Are you familiar with any of the work that Reynolds did on its premiere product?

A. No.

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Q. Do you know who Dr. Laura is?

A. Who?

Q. Dr. Laura?

A. No.

Q. Schlessinger?

A. No.

Q. She's a psychiatrist that's on the radio. She's out of St. Louis.

A. Is that right? No, I don't know her. She's in St. Louis?

Q. I think so.

A. Huh.

MR. MAISTROS: Can we take a break?

(Whereupon a short break was taken.)

Q. (By Mr. Maistros) I just want to go back to this so there's no question on the record. You believe that anyone could be nicotine dependent under DSM-IV criteria, could be?

A. Yes.

MR. NIMS: Could I have the question back?

THE WITNESS: I'm sorry; maybe I didn't understand. Are you asking could everybody be nicotine dependent or is it possible that

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there's at least someone --

MR. MAISTROS: I read the transcripts and so maybe it was the way the question was asked or whatever, but there appeared to be inconsistent answers to the issue of where you actually stand on DSM-IV and I'm not asking you to adopt the merits of DSM-IV.

THE WITNESS: Right.

Q. (By Mr. Maistros) I'm asking you just to accept the proposition that as drafted DSM-IV insofar as nicotine dependence is concerned is something that can be utilized to determine if somebody is nicotine dependent?

A. Yes, and some people can satisfy those criteria.

Q. Right.

A. Can and did.

Q. And that's true for the criteria for heroin dependence, cocaine dependence, or alcohol dependence?

A. Yes.

Q. Just because you have a criteria doesn't mean everybody who uses alcohol fits the criteria?

A. Correct.

Q. Thank God.

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Source: https://www.industrydocuments.ucsf.edu/docs/vtxl0001

Now, is there a place for the word "addiction" still in 1997 psychiatry?

A. I think that the use of the term "addiction" has become so broad and ambiguous that it now loses its meaning and in addition to the original reason that the mental health community moved away from using the term "addiction" because it was pejorative and countertherapeutic, now you've got the problem of just lack of specificity. It's just essentially almost all inclusive of anyone with any repetitive behavior. I don't think it's useful to discriminate people who are unable to control their desire for a substance and those who exercise a voluntary choice to seek satisfaction from use of a substance.

Q. If in 1988 the surgeon general had come out with report entitled "Nicotine Dependence" would you quarrel with that report if everything else in that report was the same?

A. I wouldn't quarrel with the title. I'm not sure what the rest of your question asked me to endorse but.

Q. The '88 report I'm sure you're aware --

A. Right.

Q. -- makes a finding that nicotine is

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Source: https://www.industrydocuments.ucsf.edu/docs/ytxl0001

addictive, that nicotine is a substance in tobacco that makes tobacco addictive; are you familiar with those findings?

A. Yes.

Q. Everywhere in that report instead of using, including the title, if the surgeon general had said nicotine is a dependence-producing substance, would you have a quarrel with the '88 report?

MR. NIMS: Objection.

THE WITNESS: Yes, I would still and actually to be clear about that answer, many of the basic assertions of that '88 report are summarized by Fiore and Henningfield, for example, in their statements in Hoskins. And I gave specific responses to those claims in my statement that would represent what I quarreled -- would quarrel with. So it's not just equating addiction and dependence, it is basically oversimplifying the nature of the dependence pattern and what generates it and sustains it to just being something related to nicotine levels and things associated with that.

Q. So it's more than the surgeon general's use of the word "addictive" that you quarrel with insofar

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as the '88 report is concerned?

A. Right.

Q. You did not contribute to the '88 report?

A. No.

Q. You were not asked to contribute?

A. No.

Q. Do you know if the American Psychiatric Association contributed to the '88 report?

A. I don't recall a specific role for the APA.

Q. Were you a fellow of the APA in 1988?

A. Yes.

Q. How many fellows of the APA were there?

A. Gosh, I don't know.

Q. In '88?

A. Um, I honestly don't know. I think it may be -- I'm just not sure.

Q. Did the American Medical Association contribute to the '88 report in any fashion?

A. It's an official publication of the surgeon general and I just don't remember what role the other organizations like the AMA or the APA may have had in relation to it.

Q. Do you know which organizations contributed to the '88 surgeon general's report?

A. Well, my understanding as it wasn't a

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matter of organizations contributing as much as individual experts in particular areas contributing information. It may have been that there was a role of organizations in bringing experts forward or helping identify experts but --

Q. Do you know --

A. -- I don't remember that process. I wasn't concerned with that issue, how it got to be.

Q. Do you know any of the individuals that contributed to the '88 report?

A. I believe Elvin Pomerleau, who is someone that I collaborated with, is a contributor to the '88 report.

Q. How do you spell his last name?

A. Pomerleau P-O-M-E-R-L-E-A-U, he has used my personality measures in some of his subsequent research on dependence and contributed to the '88 report.

Q. And you're much too young to have contributed to the '64 report; is that correct?

A. I was just barely in medical school at that time.

Q. When was the first time you read the '64 or '88 report?

A. In the summer of '66 when I was at the

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University of California at Berkeley in training in public health epidemiology, one of my instructors was -- a couple of my instructors had been contributors to the 1964 Surgeon General's report. I'm blocking on the fellow's name. He was head of Public Health at Minnesota, I believe, and we went through that report at that time.

Q. When was the first time you read the '88 report?

A. I think in 1992.

Q. And what was the occasion?

A. I was updating myself about information about cigarette smoking in connection with tobacco litigation.

Q. In '88?

A. Did I read it then?

Q. I'm sorry; in '92 you were doing that?

A. Yes.

Q. Was that in preparation for one of cases you cited?

A. Cooper.

Q. Who provided you a copy of that surgeon general's report?

A. I don't remember actually how I obtained it. I obtained some information with the help of

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legal counsel, but also some of it I obtained directly myself from the library. I don't know where that one came from.

Q. You don't recall if you had a copy of the '88 report at the time?

A. I don't -- I'm sure I did not have it already.

Q. Did you ever read the '88 report prior to becoming involved in assisting tobacco companies in defending litigation?

MR. MURPHY: Objection to the form of the question.

THE WITNESS: No, I was aware of the issues and had had prior discussion regarding the issue of the choice of the word "addiction" in the title in connection with discussions that I had as a consultant with the World Health Organization prior to that time because prior to that time two things had led me to give a lot of consideration to this issue of responsibility.

One was the serving as a consultant on the use of extending the term "dependence" to a variety of substances, and it was our

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decision in WHO that the word "addiction" was counter therapeutic and should not be used. That had nothing to do with the tobacco litigation. And second, my findings about the strength of genetic factors in alcoholism led a large number of defense attorneys to request me to serve as an expert consultant in arguing that hereditary factors in alcoholism that their clients were not responsible for their behavior, and I declined all of these requests because it was then and is now my feeling that responsibility for individual choice is key and that the existing existence of prior genetic or personality factors does not eliminate that responsibility.

Q. (By Mr. Maistros) You then espoused the view that a person's decision to smoke is a matter of choice?

A. Yes.

Q. You avow a similar view with respect to a person's decision to use heroin? And I'm talking about continue to use heroin and continue to smoke?

A. Heroin is more complicated because you know our -- most people who abuse heroin regularly

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actually have antisocial personality disorder and as you know, the law is that if someone is antisocial personality disorder, that does not absolve them from responsibility for their antisocial acts. And it's also our -- the legal precedent that if you make a choice to use heroin or alcohol in an intoxicated state, then you do things that lead to damage, you're then responsible for that because you were responsible when you took the initial decision to start using alcohol or heroin.

Q. Let me -- you can answer if you think I'm interrupting you, but to cut it short, my question really goes to when I asked you originally you espouse the view that smoking is an individual choice?

A. Yes.

Q. The decision to continue smoking; correct?

A. Yes.

Q. I'm not looking in the criminal context. I'm looking in the medical/physiological context. Is the use of heroin a decision of an individual choice, too, continued use?

A. Yes, I think nicotine more clearly than any other substance that is listed in DSM-IV as dependence producing is a matter of individual choice

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because it is the one, the only one, that does not have an intoxication syndrome associated with it. And I think that fact that then people are still able to process information intellectually with a clear mind is a key reason to distinguish and to set apart nicotine from other substance dependencies even if you, you know, accept that concept.

It's still different because even in DSM-IV it's clear that nicotine dependence is not associated with an intoxication and that means then that the person still has retention of their faculties for reasoning and their capacity to make informed choices to start or stop.

Q. Well, isn't intoxication just one of seven criteria listed to determine whether or not a substance is dependence producing?

A. No, actually it's not a part of the process, but if you then look at the associated syndromes that go with dependence, nicotine is the only one that does not have an intoxication syndrome as part of it.

Q. But the criteria to determine whether or not a substance is dependence producing among the seven criteria listed intoxication is not even in there; right?

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A. Right. It's not even in there.

Q. So you could have a substance, such as heroin or cocaine, go through the seven criteria and determine it's dependence producing without ever getting to the issue of intoxication?

A. Exactly.

Q. You could do that with nicotine, too?

A. Exactly.

Q. So all the intoxication criteria does, does it not, is confirm the level of dependency or the seriousness of dependency or whether you call it addictive.

MR. NIMS: Objection.

THE WITNESS: Whether I thought it --

MR. MAISTROS: It's sort of a question. If you agree with it, you could say I agree or I disagree, you've said something I disagree with.

THE WITNESS: I disagree.

Q. (By Mr. Maistros) Okay, tell me why you disagree.

A. You -- I think, as I understood what you said, actually made two assertions and one is that the severity of dependence leads to increasing probability or likelihood of intoxication and that

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perhaps also then increasing levels of dependence would lead to increasing loss of control.

Q. Okay. Then I misspoke. That's not what I meant. All I want to clarify is that as a psychiatrist, you or anyone else could evaluate whether or not a drug is dependence producing under DSM-IV without ever visiting the issue of intoxication?

A. Yes. But you could not address the questions of whether it was an addiction as described in 1964 in the surgeon general's report.

Q. We don't care about '64, at least I don't, and I guess in New York they don't care about pretty much anything before 1980, in Ohio I'm not sure when we're starting, but I'm not interested for the moment in the use of the word "addiction."

A. But you brought this up under the subject of responsibility and choice, and whether you're able to think clearly is a part of your responsibility for informed choices, I believe. And intoxication interferes with that and nicotine is the only substance listed as dependence producing that does not lead then to impairment in your ability to reason, and I think that's a big difference.

Q. What does somebody mean when they say

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Source: https://www.industrydocuments.ucsf.edu/docs/xdxl0001

psychoactive effects of nicotine?

A. Actually, it's very broad and all it means is that it leads to some change in your psyche or your personality or your emotions or your ability to think, so some change in the central nervous system, generally that's associated with a change in mood.

Q. Nicotine does have psychoactive effects; does it not?

A. Yes.

Q. As does heroin?

A. Yes.

Q. As does cocaine?

A. Yes.

Q. As does alcohol?

A. Yes.

Q. Are you aware of what research Reynolds or any other defendant has done to determine what effect a different level or differing levels of nicotine have on the extent of pyschoactive effects?

MR. MURPHY: Objection; lack of foundation.

THE WITNESS: No.

Q. (By Mr. Maistros) Are you aware of what research Philip Morris has done to determine minimum number levels of nicotine needed to addict people?

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MR. ARCHIE: Objection.

MR. MURPHY: Objection.

THE WITNESS: No.

Q. (By Mr. Maistros) Were you aware that Philip Morris was engaging in such research?

MR. ARCHIE: Objection.

THE WITNESS: No.

Q. Do you know if there's is minimum level of nicotine that is required before people become dependent upon nicotine?

A. I'm familiar with articles by Henningfield for one, I forgot the other fellow's name, trying to figure out some level of nicotine intake per day that would be below a threshold for dependence. And the idea is to look at people who are chippers or who may, you know, maybe smoke maybe five cigarettes a day, but then, you know, can take it -- smoke it one day and not for several days, but may do it once every month or every once in a while so that there's no pattern of dependence. What I would say about that kind of research is that it does not take into account the individual differences in personality that seem to be a more substantial modulator of the patterns of use and abuse and that, as discussed in my article, has more to do with your temperament

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configuration. If you're -- we found, for example, that people with antisocial personality disorder are those who are most likely to be regular light smokers or to chip. They don't have either high harm avoidance, which makes them anxiety prone, but they do have high novelty seeking, which makes them be very curious and adventurous. And so the personality traits probably have more to do with the patterns of use than do the levels of nicotine in my opinion.

Q. Again, you've got no research that would either confirm or deny that insofar as a role nicotine played?

A. Um --

Q. Nicotine.

A. What -- indirectly you can say that if, in fact, the personality traits are good predictors of variation in the pattern, then that is at least something that has to be taken into account.

Q. I agree with that and that's true you believe that with respect to cocaine, heroin, and alcohol, too; do you not?

A. Yes.

Q. Okay. So I mean that's not a unique theory to nicotine?

A. Right.

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Source: https://www.industrydocuments.ucsf.edu/docs/bdxl0001

Q. What I'm saying is you've done no comparison analysis to determine if it's personality or nicotine, a chemical compound, and it's biological effect on the body?

A. That's right. All I'm saying is that in doing those studies, you would have to take into account the personality of the individual and that hasn't been done before.

Q. You don't know if the tobacco companies have done that?

A. Well, I don't know -- you know, absence of proof is not proof of absence, and I have not investigated their records systematically.

Q. Absence of proof is not what?

A. Absence of proof is not proof of absence and so I can't logically say that they haven't done it.

Q. Sounds very lawyer-ish?

A. It's the logician in me.

Q. Do you know which entities in the United States have distributed more nicotine than any other entity in the United States?

MR. NIMS: Objection.

THE WITNESS: No, I don't actually.

MR. MAISTROS: If you have to guess,

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Source: https://www.industrydocuments.ucsf.edu/docs/dxjl0001

you think tobacco companies might be up there?

THE WITNESS: Oh, you mean as a whole?

Q. (By Mr. Maistros) Yeah.

A. Well, I'd certainly have it on my list. I don't know if nicotine is -- I hadn't thought about it in those terms. I don't know whether there is nicotine in other chemicals that the chemical industry as a whole distributes or fertilizer. I haven't even thought about it; I'm sorry.

Q. What uses does nicotine have in 1997 in this country?

A. Gosh, I'm sorry; you're beyond my expertise here. I can try to think about it and give you an intelligent answer, but it's not going to be authoritative.

Q. Do you know of any therapeutic uses related to nicotine?

A. Oh, therapeutic uses. I can't think of any.

Q. Okay. Now, in terms of the smoking population out there, what you did in Exhibit 5 was try to arrive at a percentage of that smoking population that at least as DSM-IV characterized it was nicotine dependent; correct?

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MR. NIMS: Objection.

THE WITNESS: Yes.

Q. (By Mr. Maistros) Now, when you did this study, you did not know who you would be sending this to originally?

A. Not as individuals. I just wanted a population representative of the general population, sample representative of the general population.

Q. Are there people other than you that believe that the DSM-IV nicotine dependence criteria have a value?

A. Have a what?

Q. Value.

A. Have a value?

Q. Yeah. Was there anyone out there that believes that DSM-IV nicotine dependence criteria serves some purpose?

MR. NIMS: Objection.

THE WITNESS: I think there are certainly people who do work on nicotine dependence, who -- probably those who -- especially those who contributed to the nicotine dependence criteria work on DSM-IV, would think it has value.

Q. If those people were to send out your 11

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questions on page 23?

A. Uh-huh.

Q. Those people would anticipate, would they not, that the responses would be a pretty good indicator if somebody was nicotine dependent?

MR. NIMS: Objection.

MR. MAISTROS: Under DSM-IV.

THE WITNESS: Well, again, I think this questionnaire is fair to use in a general population sample where there is no reason for bias. I think any epidemiologist even if they were an advocate and believer in the criteria should be or would be concerned about possible biases in a litigation for use of this say in a litigation situation or any other situation where the person stood to lose or gain as a result of their answers because that's the vulnerable thing in a self-report questionnaire unless you've got the opportunity for independent corroboration. That's the main thing that I would emphasize about that these questionnaires are fine and whether you believe those criteria or not, it will serve its purpose to elicit reliable data as long

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as there's not the source of bias.

Q. There --

A. There's always bias if someone stands to lose or gain from their answers, so we can only do this kind of questionnaire research in a situation where there is no such bias.

Q. Is it your testimony you couldn't evaluate whether somebody was nicotine dependent regardless of the amount of time you had to ask them questions or the questions you could ask them if there was somehow some bias in the process?

A. Well, give you an example, in Hoskins Mrs. let's see -- what is her name. I guess actually it is -- Waltina Brown claimed that she was smoking a pack and a half of cigarettes a day and yet her medical records prior to the litigation consistently indicate that she was smoking half a pack a day and she gave other statements that are inconsistent with, for example, when Dr. Fiore had published his findings about nicotine dependence, I don't think you can have confidence in her self-reports, and it would take much more thorough evaluation of the records to try to make sense of what's true and not true so just because someone says something, if they know they stand to gain in some way, you better be careful and

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it would be prudent to have independent corroboration whenever there's such sources of bias. I think she as a good example of this problem of self-report limitations.

Q. Are you talking about the extent of smoking, the frequency, or what?

A. Well, if someone doesn't even give you an accurate account of how much they're smoking, you really probably can't count on them to be giving other details. Likewise in Chamberlain, Mrs. Wohleber -- is that how you pronounce her name, W-O-H-L-E-B-E-R or U-R -- her memory is so -- or actually all the plaintiffs for which we had records in Chamberlain seemed to have a selective memory problem in that they can't remember a lot of things quite often that are informative about patterns of use and problems, and Mrs. Wohleber couldn't even remember how much she was smoking during the past year. Someone who seems to lack that kind of candor or who has such selective memory problems, I think you would have to be careful about evaluating their self-reports.

Q. Now, you've read the depositions of the plaintiffs in both cases?

A. Yes, sir.

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Source: https://www.industrydocuments.ucsf.edu/docs/ytxl0001

Q. All the plaintiffs?

A. Yes, sir, well -- four in Chamberlain and three in Hoskins. I believe those are the only ones that I've been provided.

Q. I notice there's no medical records in either of those files; did you review those?

A. No, I did not, and I in particular in the Chamberlain case before I could come to any conclusions on the individual subjects, I would really need to see those medical records. I consider what I've done so far on those plaintiffs as quite preliminary because there's so much memory problem in those cases that I felt that I needed the records very much in order to try to make sense of what that was all about.

Q. In Chamberlain you could not offer an opinion on whether any of the plaintiffs are nicotine dependent?

A. Without seeing the medical records, I really don't think I should because again, primarily there's problem of memory.

Q. And in Hoskins?

A. I think I was more impressed by the consistency and candor of the information about Mr. Hoskins and Mr. Aubain, and I think it's more

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clear in those cases, and so in my statement I did offer an opinion about those. Although, I think even there it would be helpful to have more detailed information, but I have the impression that those would probably be -- that the records would be consistent with what they said in their self-report depositions.

Q. Okay. Now, did you make a medical judgment that these plaintiffs in Ohio were not worthy of belief?

A. What I would say is that what I've seen so far is not adequate for me to come to a conclusion one way or the other and that I really then need to read the records to see whether there's some reason to give credence to their frequent statements of I don't remember, I don't recall, I was just struck that it was unusual that all four of the plaintiffs said that so often and so selectively.

Q. Is it your opinion that the -- I'm sorry, the plaintiff in New York, was it Brown?

A. Yes.

Q. Is not worthy of belief?

A. There's enough inconsistency, as I said in my statement, that I couldn't feel confident that she was reliable in her self-reports. I'm not even sure

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she would meet the originally proposed class criteria.

Q. And Hoskins and --

A. Aubain.

Q. Aubain you did express an opinion?

A. Yes. I believe they meet the class criteria, but I think that in my opinion they both were capable of stopping smoking at any time that they chose to do so, and Mr. Aubain certainly did that for a year when he had the incentive of wanting to get a reduced life insurance policy, so he stopped for over a year in order to qualify for that without any -- successfully, and Mr. Hoskins did stop at times, but it was also clear from his statements that he chose despite encouragement by his family to continue to smoke because he liked to smoke. I did not regard that as compulsive use. I thought that was a matter of choice.

Q. Now, in those files there's the -- and you have not reviewed all of the class reps depos in Ohio; correct?

A. The only ones that I had were those -- were the four. Let's see, I think that's Chamberlain, Criden, Shepard, and Wohleber.

Q. You haven't reviewed Rubineau?

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A. No.

Q. And the depos that are in the files in front of you, the Hoskins and Chamberlain files, are those all your stickies on all those depos?

A. Yes, sir.

Q. When were they put on?

A. Just in reviewing them. That would have been in Chamberlain that would be would have been in October and November.

Q. Of this year?

A. Yes. I didn't have them before the deposition that was originally scheduled and they were sent to me when we had more time when that deposition was canceled and I went through them after that.

Q. So in Chamberlain your report was prepared without reading any of the plaintiffs' depos?

A. That's correct. It only bears on the class action issue and not on the particular cases.

Q. And what else did you rely upon in preparing either of the reports, the New York and Ohio reports, other than the plaintiffs' depos?

A. Oh --

Q. Would you like to read the reports?

A. Well, I had the expert reports, Burns and

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DeNelsky in Chamberlain and Henningfield and Fiore in Hoskins and then I had also begun to analyze the survey data about cigarette smoking. I referred to that in the Hoskins.

Q. Anything else?

A. And then my reading of the literature as I cited in the reports. Surgeon general's reports, articles of Fiore.

Q. Have you actually read the '88 surgeon general's report beginning to end?

A. Couple of times. Please don't make me do it again.

Q. Now, what were you told was the Ohio, proposed Ohio class definition?

A. Let's see. Do you mind if I get it out?

Q. Go ahead.

A. The class definition was a) all nicotine dependent --

Q. I'm sorry; what are you reading from?

A. I'm sorry; this is from my first page of my declaration and expert's report.

Q. Why don't we mark it seven, will be the Ohio report.

(A certain document was marked Exhibit Number 7 for

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identification by the Reporter.)

THE WITNESS: I referred several times to Hoskins. Did you want to mark that one?

Q. (By Mr. Maistros) It actually has your CV attached to it.

A. Did you want to mark the Hoskins?

Q. Is that out of your file?

A. Yes, it is.

Q. We'll leave it in there. I'll mark the copy I brought.

A. Okay.

Q. We'll mark Hoskins as eight. _

(A certain document was marked Exhibit Number 8 for identification by the Reporter.)

THE WITNESS: On the first page of my declaration I summarized my understanding of the way the class is defined in the complaint and it's a) all nicotine dependent persons who are residents and/or citizens of the state of Ohio who have purchased or smoked cigarettes manufactured by the named tobacco companies; and b) is their estates, representatives, and administrators of these nicotine dependent smokers; and c) is the

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spouses, children, relatives, and significant others of these nicotine dependent cigarette smokers as their heirs or survivors.

Q. Now, before you go on, you have no expertise in the definition of a class, I presume?

A. No, other than its clinical implications and how it bears on psychiatric diagnosis.

Q. Have you ever read rule 23, Federal Rules of Civil Procedure?

A. No.

Q. Do you have any idea what the requirements are for a class?

A. I know I've had discussions of these issues with the attorneys for RJ Reynolds and other companies. I certainly am not an expert on it. We've had discussions about whether this would be a workable class definition and what it's implications would be as to the validity of the class.

Q. I'm sorry if I asked you this, somebody will remind me. In paragraph one of the National Institute of Health have they taken a position on nicotine dependence?

A. NIMH did you say? National Institute of Mental Health?

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Q. You say you're a consultant to the National Institute of Health.

A. Oh, okay, right.

Q. Have they taken a position on nicotine dependence?

A. I think that the National Institute of Drug Abuse, NIDA, which is one of the divisions of NIH, supports the general approach of the government that funds it, as you might imagine, and that position is generally to support the positions of other branches of government, such as the surgeon general and so the politically correct position for NIDA is that nicotine dependence is a major public health problem.

Q. So that's yes?

A. Well, yes.

Q. Now, were you provided a copy of the plaintiffs' complaint in Chamberlain?

A. Yes.

Q. Do you have that copy with you?

A. Class action allegations.

Q. Probably long. I'll mark Exhibit 9. Is this a copy of the complaint you were provided?

A. Yeah, let's see. Let's just see if this is the -- I'm trying to remember what the relationship of this is to that. I think this may be a section.

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Yeah. Yes. I don't know what this is. Oh, that's it, okay. All right, okay.

Q. What is the page of that?

A. It's just one -- I don't know. I think I made a copy of a page. This is actually Dr. Burns' statement and I had pulled off the page that had the summary of his -- the summary of the class.

Q. Is this page 19 here the same as page 19 in the complaint?

A. That's what I was trying to figure out if it was. It's a different page 19 so I'm not sure where that comes from.

Q. Have you been provided copies of any other complaints in Chamberlain?

A. No.

Q. Amended complaints?

A. I don't believe I've seen that.

Q. Your expert report, in any event, is based upon Exhibit 9 in front of you?

A. Yes.

Q. Who put the yellow stickers on Exhibit 9?

A. I'm sorry?

Q. Who put the yellow stickers on Exhibit 9?

A. I did.

Q. How did you select what to put stickers on?

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A. As I read through it, if something struck me as something that I would want to refer to later, I came back and this is actually, for example, the first sticker is the class action allegations and it's just whatever I thought was -- I wanted to be able to easily quickly retrieve or if I thought there were some statement that was questionable or important. I just -- it's a way of calling my attention to it, so if I go through it again, I'll be able to find it quickly.

Q. Okay. Could you go to page two of your report?

A. Yes.

Q. I'm talking about the Ohio report, which is Exhibit 7.

A. Yes.

Q. Do you see about three-quarters of the way down after it lists the proposed criteria for diagnosis of A, B, C?

A. Yes.

Q. What do you say after that, "In my view --

A. "The proposed measures in combination are not reliable diagnostic criteria for nicotine "addiction" or "dependence" and, as proposed for use, do not conform to any diagnostic criteria sanctioned

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by any official medical or scientific organization."

Q. Now, do you consider the American Psychiatric Association a medical or scientific -- an official medical or scientific organization?

A. Did you say American Medical?

Q. I'm sorry; American Psychiatric Association.

A. Yes, I do.

Q. You consider the American Psychiatric Association an official medical or scientific organization or both?

A. I do. Well, it's an official medical organization. I think they would also like to consider themselves, at least in their diagnostic classification work, as scientific.

Q. Hasn't the American Psychiatric Association sanctioned the use of DSM-IV as a diagnostic criteria?

MR. NIMS: Objection.

THE WITNESS: Yes.

Q. (By Mr. Maistros) And isn't one of the criteria listed above in paragraph two, persons who are or have been nicotine dependent as that phrase is defined under the criteria set forth in the American Psychiatric Association's Diagnostic and Statistical

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Manual of Mental Disorder, fourth edition, 1994, (DSM-IV).

A. Yes.

Q. So when you said in this affidavit, it is an affidavit; isn't it?

A. It's -- probably it's not notarized but it's a declaration and report. I did sign it.

Q. You said in this declaration and report that the proposed measures in combination aren't reliable diagnostic criteria for nicotine addiction and dependence and did not conform to any diagnostic criteria sanctioned by any official medical or scientific organization. Did you really mean to say that subparagraph c) of the proposed definition was not a diagnostic criteria that was sanctioned by an official medical or scientific organization?

A. What I'm say --

MR. NIMS: Objection.

THE WITNESS: What I'm saying there is that C by itself is sanctioned, but when you put C together with A, B, and/or C, then you get a composite class definition that does not conform.

Q. (By Mr. Maistros) Is there a suggestion in the complain that in order to determine whether the

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class fits the criteria of nicotine dependence that they have to meet A,B, and C?

A. My understanding was that if they meet any of those, it says and/or between A and B and C and so you could have one of those, for example, a medical practitioner telling you that you will have adverse health consequences unless you stop and that would meet the definition of class as I understand is it.

Q. Right. Let's just look at C. If you have a person who has been diagnosed in accordance with DSM-IV for nicotine dependence as nicotine dependent are you suggesting that that is not an official diagnostic criteria sanctioned by an official medical or scientific organization?

A. C by itself does correspond to the APA definition, which is official.

Q. And it would be an appropriate criteria by which to judge somebody as nicotine dependent if you believe in the value and efficacy of DSM-IV?

A. Those are official criteria for dependence. There's the question that I think you're alluding to in your statement to me that yes, even if you made the definition of dependence, though, that still would not necessarily bear on the issue does that diagnosis discriminate reliably between people who

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are unable to conform their behavior to their wishes from those who are exercising a voluntary and legal choice.

Q. Okay. Where does that voluntary and legal choice come into play in your psychiatric practice of evaluating somebody as dependent?

A. That is a legal question --

Q. Okay.

A. -- about responsibility.

Q. It has nothing to do, does it, with whether or not somebody is dependent upon a substance?

MR. NIMS: Objection.

THE WITNESS: No, I believe it does have something to do with mental status in that this is like an issue of informed consent or competency or responsibility in a criminal setting. You have to evaluate someone's mental condition in order to evaluate their capacity to make informed decisions.

Q. That's true not only with respect to nicotine but heroin, cocaine, and alcohol?

A. Correct.

Q. So don't we get back to the issue that you do not personally believe DSM-IV nicotine dependence

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criteria have the value that others might attribute to it?

A. Correct.

Q. But as a objective, scientific statement, the DSM-IV's are officially sanctioned criteria; are they not?

A. For dependence.

Q. Right.

A. But they also -- DSM-IV if you read it in the introduction it says very clearly that these criteria are not to be used to render -- they are not adequate to render legal opinions and that raises legal opinions like responsibility raise other issues, and it specifically disclaims that they are adequate directly for the kinds of legal questions to which they're now being applied.

Q. You don't -- you're not a lawyer; right?

A. Correct.

Q. In fact, you've declined the opportunity to present testimony where your psychiatric knowledge could assist the legal system in criminal cases; correct?

MR. NIMS: Objection.

MR. MURPHY: Objection.

THE WITNESS: I declined to offer

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opinions that I thought were invalid.

MR. MAISTROS: Okay.

THE WITNESS: You know, someone asked me to defend and I told him that my opinion will not help you because I will not support what you want me to say and so they, you know, it was -- at that point, it was their choice. I mean if they had wanted my to go, I would have thought they were a little bit crazy.

Q. (By Mr. Maistros) You would not be an advocate of the insanity defense I take it?

A. No, actually, I have, in fact, done a lot of work on the insanity defense in the past. I haven't been active in that for a while, but I do think that there are people who have mental disorders that make them irresponsible for their actions.

Q. Okay.

A. I think it has a limited but real place in jurisprudence.

Q. You are not attempting go offer an opinion in this case, are you, whether and that's Ohio whether or not a class action is an appropriate vehicle for relief for nicotine dependent people?

A. Well, what I can say, I'm not a legal

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expert, so what I can say is that I see problems with the proposed class definition because I think it would -- the only way to be sure in individual cases whether someone really merits some sort of relief as a result of their compliance would require individual review of facts to evaluate their responsibility for their decisions or their loss of control for their being able to control their cigarette smoking and if there are problems with that, then I don't see how the class approach really is feasible.

Q. Have you read the decision in New York which certified the class?

A. I've heard about it. I haven't read it, but I understand it was quite broad.

Q. And you I assume disagree with certification of the New York class?

MR. MURPHY: Objection.

MR. NIMS: Objection.

THE WITNESS: I was not asked to render an opinion about the judge's decision. I guess that will be done in Appeals Court or someplace.

Q. (By Mr. Maistros) What was your purpose in rendering an opinion in Ohio?

A. To evaluate the adequacy of the proposed

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class definition from a psychiatric standpoint.

Q. Only from the psychiatric standpoint?

A. Well, that's my expertise.

Q. Now, in your next sentence you say, "Further in my view, tobacco use is a complex biological, psychological, and social practice." What expertise do you have insofar as biological practice of tobacco use?

A. Well, I am a physician and I have expertise and knowledge about neurobiology and neurogenetics and brain organization. I have published in many of the leading journals in neuropharmacology and cognitive science.

Q. Other than the supervision of nicotine receptor research in 1990 by graduate students, have you done any work on nicotine and biology?

A. The issue of neurobiology is a little more general than that and I --

Q. Just nicotine?

A. I do have expertise in the neurobiology of the brain.

Q. That's not my question. I'm sure you are an expert. I'm asking have you done any research, clinical studies, investigations related to nicotine and its neurological effects in the brain?

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A. I have not done that directly. My knowledge of that is indirect through my reading of literature.

Q. Okay. Then what's the difference between a psychological and a social practice insofar as tobacco use is concerned?

A. There I'm distinguishing between factors that I would see as psychological like individual differences in personality that refer to the individual and social variables, such as peer pressure, social queues, cultural attitudes toward smoking that operate at a interpersonal level rather than an individual personal level.

Q. Okay. Now, then you go on to say -- let me read the whole sentence. "Further in my view, tobacco use is a complex biological, psychological, and social practice, and the assumption that some pharmacological addiction to nicotine explains tobacco use patterns is doubtful." I'm interested in the phrase "the assumption that some pharmacological addiction to nicotine explains tobacco use is doubtful." Where did you pick up that phrase?

A. Well, I wrote it.

Q. What did you mean by it?

A. This gets at the claims by experts like

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David Burns, who is associated with the 1988 surgeon general's report, and Jack Henningfield, who proposed -- and Fiore, who all proposed in both of these cases that nicotine is a principle agent that explains nicotine dependence and that who seem to in their proposals about regulating nicotine levels and so on seem to focus on nicotine as the major and sole or sole factor that explains cigarette smoking and its continuation, and what I argue is that, in fact, if that were true, then nicotine levels and nicotine placement therapy should be able to predict the people -- the ability of people to stop smoking -- to stop smoking and that simply is not the case.

Q. What do you mean by "pharmacological addiction"?

A. That's a phrase to refer to this model that Henningfield and Burns seemed to propose for cigarette smoking that it is, in fact, a matter of just -- that cigarette smoking is simply a vehicle for getting nicotine into the body and I believe that that is a gross oversimplification that does not explain the epidemiology or the psychiatry of cigarette smoking.

Q. Now, do Burns, Henningfield, and Fiore, one or all three of them, say that it's the

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pharmacological addiction to nicotine that explains tobacco use. That's all they rely upon?

A. Well, I'll give you their words.

In my Hoskins report on page three I said, "Among their assertions are the claims --

Q. Among --

A. Well, would you rather --

Q. -- that's the key -- that's the key word. Why don't you go to their report and show me where they said that nicotine addiction is attributable to the pharmacological addiction to nicotine?

A. Okay.

MR. NIMS: Is it your representation they don't believe that?

MR. MAISTROS: I'm just asking him where he got this phrase.

THE WITNESS: This is Henningfield's summary. Cigarettes and other forms of tobacco are addicting. Two, nicotine is the drug in tobacco that causes addiction. Three, the pharmacological and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs, such as heroin and cocaine. I believe those three statements

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are basically the crux of Henningfield's view or he wouldn't have summarized them in that way. So what he's really saying is that nicotine causes addiction, and what I'm saying is that is not a sufficient statement. It is his -- that's also the premise that underlies all of his writing about regulating the levels of nicotine and cigarettes and that's simply not adequate. His view is one of what I would call -- I would summarize these three points as the pharmacological addiction view point, and I think that's simplistic and erroneous and misleading.

Q. And you've never done any independent research on your own to determine what the pharmacological effects of nicotine are?

A. I have done research that shows that other factors other than nicotine --

Q. No, listen to my question very carefully. Have you done any research to determine the pharmacological effects of nicotine?

A. I've done literature research but not direct laboratory research myself.

Q. Now, do you know what pharmacological

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research any of the tobacco companies have done?

A. Not specifically. What -- there's been, you know, a lot of talk about information that might have been done and then suppressed which is now a matter of record as a result of disclosure of documents and it's my reading of the reports in '64 and '88 of the surgeon general that any information that has been released as a result of these public disclosures of drug company research has not really changed our understanding of substance dependence or addiction in either is the 1964 or 1988.

Q. Same that the general medical community whatever they knew about nicotine dependence in 1964 hasn't changed much to today?

A. That the description of the epidemiology and psychology and so on of substance dependence is, as it was characterized is '64, is I think very adequate in that there really was not a substantial change between '64 to '88 or to the present time. And our understanding of the nature of these disorders -- I mean we do have more information, we have more studies, we have a more detailed molecular, cellular characterization of some of the phenomenon, but basically we see and recognize the same kind of patterns of complex biopsychosocial interaction.

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Q. Are you talking from a psychiatric standpoint or a biological standpoint?

A. Both. I'm not saying that we haven't learned anything since '64, but what I'm saying is that the drug companies did not have information that kept us in the dark.

Q. Now, what is that statement based on? Tell me all the factors you base that statement on?

MR. NIMS: When you say drug company do you mean tobacco companies?

THE WITNESS: I'm sorry; I meant tobacco companies. It's a limited statement because I've already said that I have not done a systematic review, I'm not an expert on what the companies did and didn't know and when they knew it.

MR. MAISTROS: Could you read back his answer before I ask my question?

(The requested portion of the record was read by the Reporter.)

Q. (By Mr. Maistros) When you said drug companies you meant tobacco companies; right.

A. Correct.

Q. Now, who is "us"?

A. The scientific community at large.

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Q. And the information you're saying they did not have that did not keep you in the dark is that related to nicotine addiction or health consequences of smoking or what?

A. Nicotine and cigarette smoking.

Q. Okay. what information have you discovered that the tobacco companies had that they didn't disclose that didn't keep you in the dark with respect to nicotine addiction?

A. That's what I'm saying is that I really don't think that the information that is now in the public domain, as a result of disclosure of I guess what was considered confidential proprietary material, really changes our understanding of cigarette smoking and that if you look back at the 1964 report even, you'll see that it is a remarkable document prepared by the surgeon general and I think very accurately summarizes the health problems associated with cigarette smoking and --

Q. I'm not interested in the health problems for the time being. I'm talking about the addiction.

A. And the facts about whether it leads to intoxication or not is recognized. The facts about it being associated with repetitive use but not with intolerance to adverse effects but not necessarily to

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tolerance to pleasurable effects and the fact that there are people who have -- the fact that people did have difficulty stopping, but that it was something that is better characterized as an addiction -- I'm sorry; as a habit rather than an addiction because of the fact that we've discussed earlier.

MR. MURPHY: And I was just going to say I don't think you're doing it intentionally, but that's a couple times where you're cutting the witness off and I just wanted to remind you that the Northern District of Ohio, you know, we're talking about Chamberlain and others, passed a rule over the summer that specifically addressed that.

MR. MAISTROS: Is that politeness in depositions?

MR. MURPHY: It actually says ordinarily the witness should be allowed to finish his answer, and like I said, I don't think you're doing it intentionally.

MR. MAISTROS: Yeah, if I am, I apologize. I've read the depositions. The witness has certainly in the past known when to tell lawyers to please stop interrupting

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me, so I figured if I was doing it, he would tell me. If I cut you off, I apologize. I remember doing it a couple times and asked you if I cut you off. Did I just cut you off now? I don't remember what I even asked you to cut you off.

MR. MURPHY: You interjected in his answer and then told him he could keep going.

MR. MAISTROS: Yeah, because he went on to an area I wasn't asking him about, and I just didn't want to sit here and listen, but if you feel compelled to talk about the health issues, go ahead, but I'm really interested in the addiction issues.

THE WITNESS: Oh, I see, right. Okay.

Q. (By Mr. Maistros) What specific documents did the tobacco company suppress that you believe have now been released that did not keep you in the dark?

MR. NIMS: Objection; mischaracterizes the testimony.

MR. MAISTROS: I thought he used the word "suppress" but.

THE WITNESS: I'm really -- I'm not an

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expert -- I have actually haven't gone back and tried to pick out and see what was -- find something that may have been hidden. What I'm saying is that since that has been released, there has been no evolution of our understanding of the nature of substance dependence and there's been no change in it, and I think that even if you look at the 19 -- go back as far as the 1964 surgeon general's reports, what they say about the nature of the patterns of cigarette use are not really changed by the 1988 surgeon general's report and that's not changed to this day about dependence and addiction. The only thing that you've seen change is differences in criteria and then assertions being made that addiction and dependence are synonomous.

Q. Okay. Are you done?

A. Yeah.

Q. I want to go back, though, to your statement that the drug companies -- the tobacco companies did not have information that kept us in the dark. Do you know specifically what information the tobacco companies had?

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A. Oh, I see what you're saying. I can't say that. I don't. All I can say is that what has been disclosed does not seem to have changed our understanding of substance dependence. I can't say what if, in fact, everything that they knew has been disclosed. I'm not privy to that.

Q. Now, in the next sentence you say, going back to Exhibit 7, "In addition, a determination of who if, anyone --

A. I'm sorry; where is this?

Q. Bottom of page two, Exhibit 7, the Ohio report.

A. Okay.

Q. "In addition, a determination of who, if anyone, would be in any proposed class of addicted or dependent tobacco users would require an in-depth evaluation of the facts respecting each individual who claimed to be such a person."

A. Right.

Q. Now, did you use the word "addicted" or "dependent" tobacco user in there because you were paraphrasing somebody or do you use those words interchangeably?

A. No, I was using those because they're used interchangeably by the experts and in the complaints

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there's usually a reference to them being traded synonymously, so I'm just trying to make my statement conform to the complaints usage by the experts.

Q. Is it your understanding that for purposes of the class definition that it must be defined in such a way so that the entire universe of people that might be within that definition could be determined without an in-depth evaluation of the facts respecting such individuals?

MR. NIMS: Objection.

THE WITNESS: Make sure I understand the question. You're asking me is it my understanding that the proposed class definition would not allow for an in-depth evaluation?

Q. (By Mr. Maistros) No, let's back up. What is your main point you're making by this statement?

A. Well, what I'm saying is that in order to really know whether someone was dependent or not, you actually would have to review facts about each individual case, that it would not be sufficient for someone to simply indicate that they meet criterion A. Let's see -- I'm sorry; that for the definition of dependence, it wouldn't be adequate in my opinion for them to just say that a medical practitioner

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warned them or told them that they were nicotine dependent.

Q. How about if they met DSM-IV for nicotine dependence?

A. Well, even if that was true, that would show that they were dependent, but that wouldn't show that they did not have voluntary capability to make their choices or that they had loss of control. I don't believe that the dependence criteria even as sanctioned by the APA are sufficient to show that people have loss of control of smoking.

Q. Where does that come in to your expert opinion that the plaintiffs must show loss of control to be in the class?

A. Because all the experts, such as Burns in Chamberlain which is the one we're talking about, claim that cigarette smokers who are dependent or addicted are unable to stop smoking and that's the reason they've gotten hooked. They've become addicted and for that reason, they keep smoking. They really aren't able to stop even though they would like to stop. The claim is repeatedly over and over made that they really want to stop, but they can't because they're addicted. In other words, they've got loss of control and what I'm saying is

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that the dependence criteria are not sufficient to show that the person does or does not have loss of control.

Q. In other words, you'd be more comfortable if the class was limited to just dependence as opposed to choice and loss of choice.

MR. NIMS: Objection.

THE WITNESS: Well, even that -- no, that's not adequate. What I'm saying now is two problems. One is that the class definition doesn't really assure a reasonable standard for whether they're dependent. And then secondly, that even if they're dependent, that's not sufficient to show that they have loss of control of their cigarette smoking.

Q. I understand that and I understand that you don't agree with the DSM-IV, but there are people out there that do agree with DSM-IV; are there not?

A. As a definition of dependence but nobody thinks that the definition of dependence assures that you have loss of control and, in fact, nobody can really define --

Q. Where does loss of control come into this?

A. When your experts Burns and DeNelsky say

that dependent people are unable to stop smoking because they're pharmacologically addicted, that's when it comes in, in their words and in the class assertion that that's why people keep smoking. It's not me that's saying it, you're putting --

Q. Let's break this down then. Are you're telling me then that if you were among those people including the American Psychiatric Association that recognizes the DSM-IV as being a valid criteria that you could not define a class of people that fit that criteria?

MR. NIMS: Objection.

THE WITNESS: I'm sorry; would you repeat it?

Q. (By Mr. Maistros) Let's assume for a moment that you believe in the validity of DSM-IV; okay? Make that assumption for me just for this question.

A. Okay.

Q. After this question, we'll go back to your beliefs. Let's assume that you believe in the validity of DSM-IV. Is it your testimony that you could not conceive of a class of people out there in United States or Ohio or New York that would fit within the class of DSM-IV?

MR. NIMS: Objection.

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THE WITNESS: There are people who would satisfy the criteria of DSM-IV for dependence.

Q. (By Mr. Maistros) And you could develop a set of questions; could you not --

A. Yes.

Q. -- to figure out who those people are?

MR. NIMS: Objection.

THE WITNESS: I could develop a screening questionnaire, but then there would still be the issue of the reliability of that in the litigation situation that would require in-depth evaluation and corroboration of individual facts.

Q. (By Mr. Maistros) At the minimum, you could develop a screening criteria similar to what you did in Exhibit 5 in the summer of '95 from a psychiatric standpoint to determine such a class; could you not?

MR. NIMS: Objection.

THE WITNESS: Yes, subject to the difficulties of applying in a litigation situation where there's bias.

Q. (By Mr. Maistros) Which is something that you're not qualified to express an opinion on; correct?

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/gxvj0001

MR. NIMS: Objection.

Q. (By Mr. Maistros) You're not expressing legal opinions on the validity of the class; are you?

MR. NIMS: But he is qualified to express an opinion on bias in survey instruments, which is what he was doing.

Q. (By Mr. Maistros) Are you qualified to express an opinion on the validity of the class?

A. I really don't know how to answer that question, yes or no. I'm telling --

Q. Unlike court you don't have to do that. You can explain here.

MR. NIMS: We can all agree he is not the judge and the judge will decide if those things on which he has psychiatric opinions are of assistance in helping the judge determine whether a class action can be properly certified.

Q. (By Mr. Maistros) Would you adopt that as your answer?

A. Yes.

Q. Okay. So, as a matter of your expertise, you could offer an opinion as to whether or not a class of smokers would fit under the criteria DSM-IV for nicotine dependence?

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Source: https://www.industrydocuments.ucsf.edu/docs/dzxl0001

MR. NIMS: Objection.

THE WITNESS: Yes.

Q. (By Mr. Maistros) Okay. And again that answer assumes that you believe in the validity of DSM-IV for nicotine dependence; okay? So there's no confusion on the record, I'm not saying you do. I say your answer assumes it for purposes of the answer; do you understand?

A. Yes.

Q. You go on to say in this paragraph at the top of page three, referring to the last sentence, I assume, "This is based on the fact that every individual is unique in terms of genetic composition, education, experiences (adult and child) and level of maturity which define personality." Is that what you said?

A. Yes.

Q. What did you mean by that?

A. Well, in order to evaluate the motivation and decision-making ability of a person, you would have to not just know whether they continued to smoke or not or even their pattern of smoking, as defined in the diagnostic criteria, but you would actually have to understand their motivation, which would require knowledge of these kinds of developmental

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issues.

Q. How are you going to evaluate the reliability of the criteria in you're '95 study without understanding the genetic compensation and experiences, level of maturity, of the people responding to your survey?

A. Can't. I'm simply studying the relationships of those kinds of answers to one another, different approaches to criteria, and relationships of those to personality, which I also measured. I did measure personality.

Q. You say at the top of page four, "Most recently both the WHO and APA, American Psychiatric Association, have utilized the term "dependence" to recognize not a simple syndrome but a complex interplay of psychological, social, and biological factors in substance use behavior.

Were you state -- stating by that that recently the World Health Organization has used the word "dependence" insofar as nicotine is concerned or just dependence?

A. There I was referring to the shift from using the word "addiction" to using the word "dependence" and the explicit disavowal of the use of the word "addiction" because of its

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inappropriateness.

Q. Didn't the World Health Organization in fact use "dependence" back in '64?

A. The switch was made later. The WHO in the early 1980's, around the time of DSM-III was, in fact, advocating dropping the use of the word "addiction" and using the word "dependence" more consistently for substance abuse. There was some times use of the word "dependence." The important thing was to stop using the word "addiction" because of its false implications.

Q. In the middle of your paragraph you say, "A substance is traditionally considered to be addictive only if it causes a) intoxication manifest by impaired cognition and judgment; b) default of social and occupational responsibilities; and c) physical dependence manifest by a consistently reproducible withdrawal system; and d) tolerance." Where do you get that from?

A. That's a summary of a traditional picture of an addict, which was summarized, for example, in the 1964 surgeon general's report. But it wasn't -- it didn't originate with the 1964 surgeon general's report that was, in fact, that is the image of an addict.

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Source: https://www.industrydocuments.ucsf.edu/docs/vdxl0001

Q. Are you talking about image from a public perception standpoint or --

A. And criteria.

Q. -- is this a scientific definition of addiction.

A. It's scientific. It's also the popular image that's evoked because that's the picture that the scientists have characterized addiction by.

Q. And it's your testimony here today that in order to be considered -- scientifically considered addictive, you have to meet all four of these?

A. That was the 1964 surgeon general's definition that would require all of those features. I think that what you have to remember is that addiction is a concept. There is no pathognomonic biological or psychological criterion for it. Dependence is a concept and we have to evaluate these concepts in relation to some particular objective. If your objective is to determine whether someone is responsible for their choices like in smoking, then you would need to consider features that would be predictive of those kinds of choices.

Q. Okay.

A. And these are the kinds of features that I think would really show that someone is not

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Source: https://www.industrydocuments.ucsf.edu/docs/ytxl0001

responsible.

Q. Other than the '64 surgeon general's report, what authoritative scientific text could I pick up that would tell me all four of these have to be met before something's considered addictive?

A. Unfortunately, you won't find anything that specific because the traditions of diagnosis at the time were much looser than they are currently and even at that time it was DSM-II that was operative as the official criteria, and DSM-II uses this concept but it doesn't give explicit operational criteria the way DSM-III and IV did. So you won't find rules like that at that time. It just -- it was not the standard at the time.

Q. Does DSM-IV have any reference to addictiveness that bears any relation to these four criteria today?

A. Some relation but not exact, the closest that it gets is to sub type dependence into those with and without physiological dependence, which means withdrawal and tolerance. So it gets two of those, but it doesn't and it would include social and occupational impairment but not necessarily the kind of default of responsibilities and it wouldn't require intoxication at all. But we've gone over

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those kinds of issues before I think.

Q. Okay. Is your quarrel with the use of the word "addiction" by the experts in Ohio simply one of is semantics like it was -- I'm sorry let's start over because that wasn't your answer.

Is your quarrel with the use of the word "addiction" by the Ohio experts such that if "dependence" was used instead of "addiction," you would have less of a problem with that?

MR. NIMS: Objection.

THE WITNESS: That's not the only -- that's not the only problem. What I see happening is that people are trying to use the dependence criteria to do something it does not do and wasn't designed to do and that is to identify people who supposedly have loss of control of their decision to continue or to stop smoking. That's the fundamental problem.

Q. (By Mr. Maistros) But it's your understanding this loss of control of decision is interjected solely as a result of the plaintiffs' experts?

A. No, it's a part of the complaint.

Q. Is it part of the class definition?

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A. Well, let me see if I can find -- okay. The complaint itself, page 26, this is Exhibit 9, section 38, summarizes the same points that are in the Henningfield summary in Hoskins and the Chamberlain section 38 referring to the surgeon general's reports, repeats that cigarettes are addicting, that nicotine is the drug in tobacco that causes addiction, and the pharmacological processes that determine tobacco addiction are similar to those that determine addiction to drugs, such as heroin and cocaine. Those same claims are made here in Chamberlain in the basic complaint.

Q. Okay. Again, my question is do you know and if you don't, just say you don't. Do you know if loss of control is a component of the class definition in Chamberlain as proposed?

MR. MURPHY: I'm going to object to the form. I think part of the problem is that the multi-multi-page complaint?

Q. (By Mr. Maistros) Well, let's make it simple. You have outlined in your report the proposed class definition if you go to page two at the top in terms of the criteria for diagnosis; do you see that.

A. I'm sorry; what page?

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Q. Your report. Go to your report in Ohio, Exhibit 7, page two?

A. Okay.

Q. Didn't you in there paraphrase what the proposed class would include?

A. What I am saying, and I just was trying to find the section where it makes it explicit, is that I believe that the proposed class definition implicitly assumes that loss of control is involved in nicotine dependence and/or addiction but.

Q. Doesn't state that, though, does it?

A. Well, that's what I'm trying to find. Certainly that is -- that claim is made by both the experts and by the surgeon general's report, which are quoted in the complaint. There's no question about that, unless you want to -- if I'm mistaken, if you want to correct me and say that you do not think that loss of control is required --

Q. I'm just asking you --

A. Or that nicotine dependent people don't --

Q. You keep interjecting and I'm asking you do you believe that that is in the stated written definition of the proposed class?

MR. MURPHY: I'm going to object. I mean I think there's terms in the proposed

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class or defined in other parts of the complaint and I think it's an unfair question given the length of complaint.

Q. (By Mr. Maistros) There's no right or wrong here. If you're telling me that you believe that that is part of the stated class definition of the complaint, that's your answer, and I mean the complaint is what it is. We can all read it. It's in there somewhere, I'm sure, but you paraphrase it in your report and you don't make reference to that. That's why I'm wondering why you keep interjecting that phrase.

MR. MURPHY: Again, I'm going to object to your question about what his report does or does not make reference to. I think the report speaks for itself.

THE WITNESS: Well, it says here that the tobacco, on page 54, the tobacco industry engaged in an ongoing conspiracy to actively misrepresent, omit, and conceal the truth about nicotine in order to sustain the addictions to exist -- of existing cigarette smokers and to hook thousands of new smokers everyday. Those words are other ways of talking about loss of control. In other

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words, the idea is addiction and hooking, that these are then people who once they start are unable to stop.

Q. (By Mr. Maistros) Do you under --

A. That's what I mean when I say loss of control and I would say that when I said a loss of control, I say that that is the concept that is embedded in this statement on page 54 of the complaint.

Q. Do you understand what the purpose of a class definition is?

MR. MURPHY: Jack, I'm going to make another objection to this that we served a set of class certification interrogatories on plaintiff that would have from our position hopefully shed light on the class definition, and we did not get answers to those. So I think that's another objection to raise here.

MR. MAISTROS: All right.

MR. MURPHY: We asked the plaintiffs to tell us what the class definition was and we got nowhere.

Q. (By Mr. Maistros) Do you understand what the purpose of class definition is?

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A. It's -- my understanding is that it is a set of criteria to define a group of people who are either in the class or outside of the class, so that they can participate in a group complaint to receive relief for complaints alleged.

Q. And in the second page of your report you state, "Furthermore, the proposed criteria for diagnosis of nicotine dependence include" and then you list those A, B, C.

A. Uh-huh.

Q. Did you pick that out of the complaint?

A. Yes.

Q. Or did an attorney?

A. No, I did. It's right there. It doesn't take much -- it's listed the same way.

Q. And it's almost word for word that's in the complaint; is it not?

A. Yes.

Q. Now, is it your understanding that that is how the class would be decided if they fit that criteria?

MR. NIMS: Objection. Again, I'm going to object in that we tried to ask that of plaintiffs --

MR. MAISTROS: I'm not asking what he

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Source: https://www.industrydocuments.ucsf.edu/docs/vtxl0001

thinks the Ohio claim should be made of. We're missing each other. I'm not asking what he thinks the Ohio class consists of.

MR. MURPHY: Let me put my objection on the record that I think it's unfair to ask him these questions when plaintiffs themselves won't define for us what the class is and when we've specifically asked in paragraphs 28 and 29 of the complaint set forth the definition of class membership that you propose and that question was not answered.

Q. (By Mr. Maistros) Did you understand my question?

A. Would you repeat the question?

Q. You listed in your report the proposed criteria. It's very accurate, it was taken right out of the complaint.

A. Uh-huh.

Q. Did you have any question that that was the proposed diagnostic criterion for this class in Ohio?

A. I understood that that was what was proposed.

Q. I'm not asking you if you agree with it. You obviously don't agree with it; right?

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A. Or that it would be what would be finally accepted, but I know it's proposed.

Q. But when you decided to list A, B, and C, did you see anything before, close to, or in A, B, and C that referenced lack of control --

MR. NIMS: Objection.

Q. (By Mr. Maistros) -- or inability to control or choice?

A. I think I've answered this repeatedly. I believe that the whole complaint and your expert statements all indicate that you're proposing a definition and alleging that it would be adequate to identify people who have become hooked to cigarettes and are unable to stop even though they wish to.

MR. MAISTROS: Okay. Obviously we're not going to finish today or maybe not obviously. I'm not going to finish today. Does anyone have objection to recessing until tomorrow morning?

(Whereby, signature was not waived.)

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I, DR. C. ROBERT CLONINGER, hereby state that I have read the foregoing questions and answers appearing in this transcript of my deposition, and that this is a true and accurate (corrected) report of said answers given in response to the questions appearing herein.

_____
DR. C. ROBERT CLONINGER

Subscribed before me this ____

day of _____, 1997.

My commission expires _____

_____
Notary Public.

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TRANSCRIPT CORRECTION SHEET

Upon reading the deposition and before subscribing thereto, the deponent indicated the following changes:

(Any misspellings may be noted once with the notation to change throughout transcript.)

Page ___, Line __, Should read:
Reason for change:

Page ___, Line __, Should read:
Reason for change:

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Reason for change:

_____
SIGNATURE OF WITNESS

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C E R T I F I C A T E

I, Christina J. Dunkel, CSR, do hereby certify that pursuant to Notice there came before me DR. C. ROBERT CLONINGER, who was by me first duly sworn of his oath to testify to the truth of his knowledge touching and concerning the matters in controversy in this cause; that he was thereupon examined upon his oath, and his examination was taken in shorthand by me and later transcribed into computer-aided transcription under my supervision, and that the deposition is a true record of the testimony given by the witness.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my seal this 29th day of November, 1997.

51770 0807

Christina J. Dunkel, CSR

OFFICIAL SEAL
CHRISTINA J DUNKEL
NOTARY PUBLIC STATE OF ILLINOIS
MY COMMISSION EXPIRES JAN. 21, 1999

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

JUDITH E. CHAMBERLAIN, et al., Plaintiffs, -v- THE AMERICAN TOBACCO COMPANY, INC., et al., Defendants.	)	CIVIL ACTION NO. 1:96CV2005 JUDGE PATRICIA ANNE GAUGHAN PLAINTIFFS' AMENDED NOTICE OF DEPOSITION OF C. ROBERT CLONINGER

Please take note that on November 13 and 14, 1997 beginning at 10:00 a.m., at the St. Louis Airport Marriott, I-70 at Lambert Airport, St. Louis, Missouri 63134, Plaintiffs in the above-captioned action will take the deposition, for the limited purpose of inquiring into class certification issues, pursuant to Federal Rule of Civil Procedure 30, of C. Robert Cloninger. Dr. Cloninger is to bring with him for purposes of this deposition each and every document reviewed by, related to and/or relied upon by Dr. Cloninger in preparation of his Expert Report. These documents are to include all drafts of the Expert Report. The deposition will be taken before a person authorized by the law to take

EXHIBIT
1
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depositions. This deposition will continue from day to day until completed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

A copy of the foregoing Plaintiffs' Amended Notice of Deposition of C. Robert Cloninger has been sent via telefax and regular U.S. Mail, postage prepaid, this 5 day of November, 1997 to:

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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

PHYLLIS SMALL and DENISE FUBINI, individually, and on behalf of others similarly situated, Plaintiffs, - against - LORILLARD TOBACCO COMPANY, INC., LORILLARD, INC., LOEWS CORPORATION, COUNCIL FOR TOBACCO RESEARCH-USA, INC. (Successor to Tobacco Industry Research Committee), AND TOBACCO INSTITUTE, INC., Defendants.		Index No. 110949/96 Judge Charles E. Ramos NOTICE TO TAKE VIDEO DEPOSITION AND REQUEST FOR THE PRODUCTION DOCUMENTS

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

MARY ANN HOSKINS, Executrix of the Estate of Edwin Paul Hoskins, WALTINA BROWN and DANTE AUBAIN, individually, and on behalf of others similarly situated, Plaintiffs, - against - R.J. REYNOLDS TOBACCO COMPANY, RJR NABISCO, INC., COUNCIL FOR TOBACCO RESEARCH-USA, INC. (Successor to Tobacco Industry Research Committee), AND TOBACCO INSTITUTE, INC., Defendants.		Index No. 110951/96 Judge Charles E. Ramos NOTICE TO TAKE VIDEO DEPOSITION AND REQUEST FOR THE PRODUCTION DOCUMENTS

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EXHIBIT 2 11/13/97

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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

SHARLENE HOBERMAN and AUDREY HULSE, as executrix, on behalf of the Estate of Lewis Hulse, individually, and on behalf of others similarly situated,	x	Index No. 110953/96
Plaintiffs,	x	
- against -	x	Judge Charles E. Ramos
BROWN & WILLIAMSON TOBACCO CORPORATION, B.A.T. INDUSTRIES P.L.C., BATUS, INC., BATUS HOLDINGS, INC., COUNCIL FOR TOBACCO RESEARCH-USA, INC. (Successor to Tobacco Industry Research Committee), and TOBACCO INSTITUTE, INC.,	x	NOTICE TO TAKE VIDEO DEPOSITION AND REQUEST FOR THE PRODUCTION DOCUMENTS
Defendants.	x	

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

ROSE FROSINA, ELIZABETH COLAVITO and ANILDA ROSS, individually, and on behalf of others similarly situated,	x	Index No. 110950/96
Plaintiffs,	x	
- against -	x	Judge Charles E. Ramos
PHILIP MORRIS, INC., PHILIP MORRIS COMPANIES, INC., COUNCIL FOR TOBACCO RESEARCH-USA, INC. (Successor to Tobacco Industry Research Committee), AND TOBACCO INSTITUTE, INC.,	x	NOTICE TO TAKE VIDEO DEPOSITION AND REQUEST FOR THE PRODUCTION DOCUMENTS
Defendants.	x	

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11/12/97 WED 14:07 FAX 212 818 0477 GOODKIND, L. RES 003

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

CATHERINE ZITO, PETER HOBERMAN, and GEORGE ELISSEOU, individually, and on behalf of others similarly situated,	x	Index No. 110952/96
Plaintiffs,	x	
- against -	x	Judge Charles E. Ramos
THE AMERICAN TOBACCO COMPANY, INC., AMERICAN BRANDS, INC., COUNCIL FOR TOBACCO RESEARCH-USA, INC. (Successor to Tobacco Industry Research Committee), AND TOBACCO INSTITUTE, INC.	x	NOTICE TO TAKE VIDEO DEPOSITION AND REQUEST FOR THE PRODUCTION DOCUMENTS
Defendants.	x	

PLEASE TAKE NOTICE, that pursuant to Article 31 of the Civil Practice Law and Rules, the testimony upon oral examination of the following persons who have been designated as expert witnesses by the captioned defendants will be taken before a notary public who is not an attorney, or an employee of an attorney for any party or prospective party herein, and is not a person who would be disqualified to act as a juror because of interest or because of consanguinity or affinity to any party herein, at the offices of Goodkind, Labaton, Rudoff & Sucharow, 100 Park Avenue, 12th floor, New York, New York, as follows:

(1) Daniel J. Acosta (Brown & Williamson) on November 17, 1997 at 9:00 a.m and continuing from day to day until concluded;

(2) Lawrence A. Carr (Brown & Williamson, Lorillard, Philip Morris and R.J. Reynolds) on November 18,

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1997 at 9:00 a.m. and continuing from day to day until concluded;

(3) Dr. Robert C. Cloninger (R.J. Reynolds) on November 19, 1997 at 9:00 a.m and continuing from day to day until concluded;

(4) Cathy L. Ellis, Ph.D. (Philip Morris) on November 20, 1997 at 9:00 a.m and continuing from day to day until concluded;

(5) Ronald Faber (Brown & Williamson, Lorillard, Philip Morris and R.J. Reynolds) on November 21, 1997 at 9:00 a.m. and continuing from day to day until concluded;

(6) William Jacob George (Brown & Williamson, Lorillard, Philip Morris and R.J. Reynolds) on November 17, 1997 at 9:00 a.m. and continuing from day to day until concluded;

(7) Harvey M. Hammer (Brown & Williamson, Lorillard, Philip Morris and R.J. Reynolds) on November 14, 1997 at 9:00 a.m. and continuing from day to day until concluded;

(8) Lucy L. Henké (Brown & Williamson, Lorillard, Philip Morris and R.J. Reynolds) on November 13, 1997 at 9:00 a.m. and continuing from day to day until concluded;

(9) Edward V. Morse (Brown & Williamson, Lorillard, Philip Morris and R.J. Reynolds) on November 21, 1997 at 9:00 a.m. and continuing from day to day until concluded;

(10) Edward T. O'Donnell (Brown & Williamson, Lorillard, Philip Morris and R.J. Reynolds) on November 24, 1997 at 9:00 a.m. and continuing from day to day until concluded;

(11) Michael B. Parish (Brown & Williamson, Lorillard, Philip Morris and R.J. Reynolds) on November 17, 1997 at 9:00 a.m. and continuing from day to day until concluded;

(12) James F. Glenn, Ph.D (Council for Tobacco Research) on November 17, 1997 at 9:00 a.m and continuing from day to day until concluded;

(13) Ronald J. Lukas, Ph.D. (Council for Tobacco Research) on November 18, 1997 at 9:00 a.m and continuing from day to day until concluded;

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(14) Harmon McAllister, Ph.D (Council for Tobacco Research) on November 19, 1997 at 9:00 a.m and continuing from day to day until concluded;

(15) Suzanne Oparil, M.D. (Council for Tobacco Research) on November 20, 1997 at 9:00 a.m and continuing from day to day until concluded;

(16) Emanual Rubin, M.D. (Council for Tobacco Research) on November 21, 1997 at 9:00 a.m and continuing from day to day until concluded;

(17) Kenneth S. Houghton, Ph.D. (Philip Morris) on November 24, 1997 at 9:00 a.m and continuing from day to day until concluded;

(18) Bradsher T. Scott (Philip Morris) on November 21, 1997 at 9:00 a.m and continuing from day to day until concluded;

(19) Alan B. Norman (R.J. Reynolds) on November 14, 1997 at 9:00 a.m and continuing from day to day until concluded; and

(20) Alexander Spears (Lorillard) on November 24, 1997 at 9:00 a.m and continuing from day to day until concluded.

PLEASE TAKE FURTHER NOTICE, that pursuant to section 202.15 of the Uniform Rules the deposition will be videotaped by Michael R. DeCheser of International Video Productions, Inc., 45 Rockefeller Plaza, Suite 2265, New York, New York.

PLEASE TAKE FURTHER NOTICE, that each of the above designated witnesses are required to produce at the offices of Goodkind Labaton Rudoff & Sucharow, 100 Park Avenue, New York, New York 10017, at least ten (10) days prior to the deposition date any and all documents, materials or

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information responsive to the request for documents set forth on Schedule "A," attached hereto.

Dated: New York, New York
October 24, 1997

GOODKIND LABATON RUDOFF
& SUCHAROW LLP
100 Park Avenue
12th Floor
New York, New York 10017
(212) 907-0700

TO:

R.J. REYNOLDS DEFENDANTS
Hugh Whiting, Esq.
Mark Belasic, Esq.
Jones, Day, Reavis & Pogue
Fax: (216) 579-0212

Harold Gordon, Esq.
Jones, Day, Reavis & Pogue
Fax: (212) 755-7306

COUNCIL FOR TOBACCO RESEARCH
Harry Zirlin, Esq.
Debevoise & Plimpton
Fax: (212) 909-6836

BROWN & WILLIAMSON TOBACCO CORP./
AMERICAN TOBACCO DEFENDANTS
Dan O'Neill, Esq.
Chadbourne & Parke LLP
Fax: (212) 541-5369

Stephan Engelhardt, Esq.
King & Spalding
Fax: (212) 556-2222

BAT DEFENDANTS
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Simpson, Thatcher & Barlett
Fax: (212) 455-2502

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LORILLARD DEFENDANTS
Alan Mansfield, Esq.
Bob Kirchenberg, Esq.
Greenberg Traurig Hoffman
Lipoff Rosen & Quentel
Fax: (212) 223-7161

Gary Long, Esq.
Shook Hardy & Bacon LLP
Fax: (816) 421-2708

PHILIP MORRIS DEFENDANTS
Sean Wajert, Esq.
Dechert Price & Rhoads
Fax: (215) 994-2222

Robert Cohen, Esq.
Amianna Stovall, Esq.
Fax: (212) 698-3599

TOBACCO INSTITUTE
Jack Yoskowitz, Esq.
Seward & Kissel
Fax: (212) 480-8421

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SCHEDULE "A"

REQUEST FOR DOCUMENTS

1. the deponent's most current c.v.;

2. a full copy of the deponent's expert report in this action with all attachments;

3. all drafts of the deponent's expert report;

4. all documents, writings, or other tangible items the deponent has prepared, received, and/or reviewed in preparing his or her expert reports or his or her expert opinions (including, but not limited to pleadings, filings, memos, correspondence, expert reports (including preliminary reports and/or drafts), deposition transcripts, videotapes, computer files, e-mail, Internet material or handouts);

5. all documents, writings, textbooks, learned treatises, materials or other tangible items (including, but not limited to pleadings, filings, memos, correspondence, expert reports (including preliminary reports and/or drafts), deposition transcripts, videotapes, computer files, e-mail, Internet material or handouts) that the deponent has reviewed and/or relied upon in connection with his or her expert reports, or his or her expert opinions in this action;

6. all documents prepared or generated by the deponent, or at the deponent's request, by others, in connection with his or her expert reports, or his or her expert opinions in this action, including correspondence with counsel;

7. all documents, writings, materials, or other tangible items related to or arising from any research or other scientific endeavor conducted by the deponent (including, but not limited to pleadings, filings, memos, correspondence, expert reports (including preliminary reports and/or drafts), deposition transcripts, videotapes, computer files, e-mail, Internet material or handouts), which forms the basis of or supports the deponent's opinions in this action.

8. documents sufficient to show how much the deponent has billed in expert or consulting fees related to any of the captioned actions;

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9. all correspondence or documents reflecting communications with anyone regarding any issue related to any of the captioned actions;

10. all articles, reports and/or papers, published or unpublished, that were prepared by or at the direction of the deponent which forms the basis or supports the deponent's expert report or opinion in these actions, including but not limited to:

(a) all drafts of all articles, reports and/or papers;

(b) any and all raw data obtained in the experimental phase of all articles, reports and/or papers;

(c) a copy of each manuscript submitted to any scientific journal prior to peer review;

(d) all correspondence or documents reflecting communications with journal editors, including, but not limited to referee of reviewer comments of any work;

(e) all research notes, tabulations, plots, graphs, analysis, informal and formal research reports, written by the deponent or someone else at the direction of the deponent;

(f) a copy of all thesis, part or all of which appears in any work; and

(g) all correspondence or documents reflecting communications with anyone regarding any research;

11. all deposition video tapes and transcripts with exhibits and/or trial testimony taken of the deponent.

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CU[redacted]TAE

C. Robe[redacted]r, M.D.

Date: March, 1997

Birthplace: Beaumont, Texas

Citizenship: U.S.A.

Address: Office: Department of Psychiatry
Washington University Medical School
4940 Children's Place
St. Louis, MO 63110
314-362-7005 (phone)
314-362-5594 (fax)

Home: 7100 Delmar
University City, MO 63130
314-863-1338

Present Position: Wallace Renard Professor of Psychiatry, also Professor of Genetics & Psychology, and Director of Center for Psychobiology of Personality

Education:

University of Texas, Austin, Texas, 1962-1966, B.A. with high honors and special honors in Plan II (Philosophy, Psychology, and Anthropology).

Washington University School of Medicine, St. Louis, MO 1966-1970, M.D.

Epidemiology Field Research Trainee, California State Department of Public Health, Berkeley, California, July 1967-September 1967.

Student Research Fellow (with S.B. Guze), Washington University School of Medicine, St. Louis, Missouri, June 1969-October 1969.

Assistant Resident-Assistant and Trainee (NIMH) in Psychiatry Washington University School of Medicine, St. Louis, Missouri, July 1970-June 1973.

Research Scientist Development Awardee (NIMH) in Quantitative Genetics, July 1975-1985.

Visiting Investigator, Population Genetics Laboratory, University of Hawaii at Manoa, July 1978-June 1979.

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EXHIBIT
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Academic Positions/Employment:

Instructor in Psychiatry, Washington University School of Medicine, St. Louis, Missouri, July 1973-June 1974

Assistant Professor of Psychiatry, Washington University School of Medicine, St. Louis, Missouri, July 1974-June 1978.

Associate Professor of Psychiatry, Washington University School of Medicine, St. Louis, Missouri, July 1978-June 1981.

Associate Professor of Genetics, Washington University School of Medicine, St. Louis, Missouri, July 1979-June 1981

Visiting Professor of Psychiatry and Genetics, University of Umea School of Medicine, Umea, Sweden, May to June, 1980.

Professor of Psychiatry and Genetics, Washington University School of Medicine, July 1981-Present.

Head, Department of Psychiatry, Washington University School of Medicine, July 1989-March 1994

Professor of Psychology, Washington University, July 1989-present.

Wallace Renard Professor of Psychiatry, Washington University, July 1991-present

Director, Center for Psychobiology of Personality, March 1994-present

Hospital Appointments:

Barnes and Allied Hospitals, St. Louis, MO
Assistant Psychiatrist, July 1973-June 1980
Associate Psychiatrist, July 1980-June 1981
Psychiatrist, July 1981-present
Psychiatrist-in-chief July 1989-

Children's Hospital of St. Louis
Psychiatrist-in-chief, July 1989-June 1991

Malcolm Bliss Mental Health Center, St. Louis, MO
Consulting Psychiatrist, July 1973-Present

Jewish Hospital of St. Louis, MO
Associate Psychiatrist, July 1976-June 1980
Psychiatrist, July 1980-Present
Director of Outpatient Psychiatry, July 1976-June 1989

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Other University Appointments and Committees:

Steering Committee Member, McDonnell Center for Higher Brain Function, 1989 - 1993

Steering Committee Member, WUMS Howard Hughes Program, 1990 - 1993

Chair, Division of Biostatistics Advisory Committee, 1989 - 1993

Member, Health Care Administration Advisory Committee, 1989 - 1993

Member, Occupational Therapy Program Advisory Committee, 1990 - 1993

Medical Licensure and Board Certifications:

State Board of the Healing Arts of Missouri, Physicians and Surgeons #32703, issued June 20, 1970

Missouri Controlled Substance Registration #210508

Bureau of Narcotic and Dangerous Drugs #AC4359419

Diplomate, American Board of Psychiatry and Neurology, 1975

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Honors and Awards:

Institute of Medicine, National Academy of Sciences, USA, elected active member, May 1989 - present

Phi Beta Kappa - 1965

Phi Beta Sigma - 1963

Alpha Epsilon Delta - 1965

Sandoz Award for Research in Psychiatry, Washington University School of Medicine (1970)

Research Scientist Development Awards:

Type 1 (1975-1980) MH-0048. The transmission and prognosis of psychiatric disorders (Quantitative Genetics and Environmental Genetic Interaction)

Type 2 (1980-1985) Genetic epidemiology of psychiatric disorders

Research Scientist Award (MH-00048)

Genetic Epidemiology of Psychiatric Disorders (1985-1989) (Resigned to accept chairmanship)

Endowed Visiting Professorships

Milton and Harriet Parker Memorial Lecturer, Ohio State University, Department of Psychiatry, September 1983 and December 1985

John Nielson Distinguished Lecturer, University of Utah, Department of Psychiatry, April 1988

Stewart Wolf Distinguished Lecturer, University of Oklahoma, Department of Medicine, May 1988

James Brady Lecturer, University of Colorado, 1989

Frank H. Luton Lecturer, Vanderbilt University, 1989

William D. Stubenbord Visiting Professor, Cornell University Medical College and the Louis Calder Foundation, September, 1991

Other Distinguished Lectureships

Sigma Xi Lecturer on Natural Sciences, University of North Carolina, October 1987

NIH Centennial Lecturer, Washington, DC, September 1987

Plenary Lecturer, Research Society on Alcoholism, June 1988

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Pfizer Visiting Professor, Columbia University and New York State Psychiatric Institute, October 1991

Gudbrandsdalen Medalist & Lecturer, Norwegian Medical Research Council, Lillehammer, Norway, 1992

Keynote Speaker, Australian-New Zealand Psychiatric Association Annual Meeting, Christchurch, New Zealand, 1993

Lederle Visiting Professor, Hospital de la Salpetriere, Paris, France, December, 1993

Honorary Doctor of Medicine (M.D. honoris causa), University of Umea (Sweden), October 1983 for distinguished contributions to genetic epidemiology of psychiatric disorders

Strecker Award (The 25th Annual Institute of Pennsylvania Hospital Award in Memory of Edward A. Strecker, M.D.), 1988 for significant contributions to psychiatric patient care and treatment by studies of the assessment and inheritance of personality and psychopathology

Edgehill Newport Scientific Recognition Award, May 1990, in recognition of outstanding contributions to the treatment of chemically dependent persons through basic research

Mortimer Goodman Memorial Award, The Alliance for the Mentally Ill of Metro St. Louis, in recognition of outstanding service as a physician, researcher, administrator, public servant and friend, May 1992

James B. Isaacson Memorial Award, June 1992, International Society for Biomedical Research on Alcoholism and National Foundation for Prevention of Chemical Dependency Disease, for excellence in scientific research into the causes of chemical dependency diseases

Samuel Hamilton Award, March 1993, American Psychopathological Association, for contributions to understanding personality and psychopathology

Adolf Meyer Award, May 1993, American Psychiatric Association, for outstanding contributions to the science and practice of psychiatry

Editorial Responsibilities:

Editor, Behavior Genetics (1980-1986)
Associate Editor,
American Journal of Human Genetics (1980- 1983)
Journal of Clinical Psychiatry (1981-1987)

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Genetic Epidemiology (1983-1991)
Human Heredity (1989-Present)
Field Editor, Neuropsychiatric Genetics, American Journal Medical Genetics (1992 -)
Editorial Boards,
Archives of General Psychiatry (1987-)
Neuropsychopharmacology (1991-)
Comprehensive Psychiatry (1992-)
Journal of Psychiatric Research (1993-)

Professional Societies and Organizations:

Advances in Neuropyschiatry and Psychopharmacology
Editorial Board - Raven Press (1991-1993)

American Association for the Advancement of Science, Member (1976-Present)
Representative of the Behavior Genetics Association Section Committee for Medical Sciences (Section N) (1986-1989)

American College of Neuropsychopharmacology, Member (1987-)
Committee on Issues of Public Concern (1988-)

American Medical Association, Member (1982-Present)

American Psychiatric Association, Member (1975-1979)
Fellow (1980-Present)

American Psychopathological Association, Fellow (1976-Present)
Membership Chairman (1978-1984)
Treasurer (1984-1990)
Vice-President (1990-1991)
President-Elect (1991-1992)
President (1992-1993)

American Society of Human Genetics, Member (1976-Present)

Behavior Genetics Association, Member (1976-Present)
BGA Representative to AAAS Section Committee for Medical Sciences
Chairman, Publications Committee (1986-1989)

Center for Advanced Study in the Behavioral Sciences,
Academic Psychiatry Consortium
(1990-1993, 1993-1996)

Eastern Missouri Psychiatric Society, Member (1973-Present)

International Society for Study of Personality Disorders,
Board of Directors - (1991 -)
President, American Region - (1993 -)

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Psychiatric Research Society, Member (1977-Present)

Research Society on Alcoholism (1981-Present)
Committee on Research Development (1984-Present)
Member, Board of Directors (1987-1990)
Committee on Issues of Public Concern (1989-91)

Society of Biological Psychiatry, Member (1977-Present)

Consulting Relationships and Board Memberships:

Consultant, American Psychiatric Association
Task Force on Nomenclature (Diagnostic and Statistical Manual - III), 1978-1980
Task Force to Evaluate DSM-III, 1983-
Committee to Revise DSM-III, 1984-1987
Task Force on DSM-IV, 1988-

Psychiatric Consultant and Member of Professional Advisory Council, Suicide Prevention Service of Madison - St. Clair Counties (1971-1993)

Psychiatric Consultant, 3rd Judicial Circuit of Illinois (1973-1974)

Special Consultant and Site Visitor, NIMH Clinical Program Projects and Clinical Projects Review Committees (1977-1980)

NIMH Psychopathology and Clinical Biology Research Review Committee:
Consultant and Committee Member (1980-Present)
Chairman, Psychopathology Subcommittee (June 1981-1983)
Chairman (June 1983-July 1984)

Scientific Advisor and Consultant, NIMH Affective and Anxiety Disorders Research Branch (1986-1989)

Scientific Advisory Board
Children of Alcoholics Foundation (1989 - present)

Consultant to Director, NIAAA (1984-Present)
Board of Scientific Counselors (1988-)

Consultant, World Health Organization (WHO)/ADAMHA Advisory Group on Diagnosis and Classification of Mental Disorders, and Alcohol - and Drug-Related Problems (1981-1985)
Consultant Psychiatrist (1993-present)

Member, Research Advisory Council, Texas Department of Mental Health and Mental Retardation (1983-1985)

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Extramural Scientific Advisor and Consultant
Chicago Medical School, Department of Psychiatry (1977)
New York University Medical School, Psychiatry (1980-82)
University of Minnesota, Dight Laboratories, Genetics (1985-88)
University of Connecticut, Alcoholism Research Center (1986-91)
University of Pennsylvania, Clinical Research Center (1987-present)
University of Colorado, Alcohol Research Center (1991-)

University of Oklahoma,
Alcoholism Research Center (1987-92)

Honorary Member - IBC Advisory Council, 1989

Scientific Advisory Board - Oklahoma Center of Molecular Medicine, 1990

Missouri Mental Health Commission - (9/26/90 - 6/28/94)

Pfizer Visting Professorship in Psychiatry Academic Advisory Committee, 1993

Research Support:
Governmental:

NIMH, MH31302, Epidemiological Genetics and Family Study, C.R. Cloninger, M.D., P.I.; 08/01/86 - 07/31/96

NIAAA, AA07982, Prediction of Alcohol Abuse in Swedish Adoptees, C.R. Cloninger, M.D. P.I.; 07/01/88 - 06/30/95

NIAAA, AA08028, Molecular Genetic Studies of Alcoholic Subtypes, C.R. Cloninger, M.D., P.I.; 12/01/88 - 11/30/95

NIMH, MH46276, Diagnostic Center for Linkage Studies of Schizophrenia, C.R. Cloninger, M.D., P.I.; 09/30/89 - 08/31/94

NIAAA, AA08401, Collaborative Studies on the Genetics of Alcoholism, Coordinating Center, Theodore Reich, M.D., P.I.; 10/01/89 - 09/30/94

NIMH, MH46280, Diagnostic Center for Linkage Studies of Bipolar Disorder, Theodore Reich, M.D., P.I.; 09/30/89 - 08/31/94

MH14677, Research Training in Clinical Sciences, C.R. Cloninger, M.D., P.I.; 07/01/92 - 06/30/97 (transferred to T. Reich, 7/1/93)

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Teaching Titles and Responsibilities:

Coursemaster, Introduction to Clinical Psychiatry - Washington University School of Medicine II (1976-1989)

Committee on Academic Review and Promotion (1976-1989)

Lecturer, Medical Genetics, Washington University School of Medicine (1980-Present)

Clinical Sciences Postdoctoral Training Program
Preceptor (1975-Present)
Psychiatric Genetics Director (1980-Present)
Overall Program Director (1985-1993)

RESEARCH TRAINEES
Current Trainees

Betty Lobos, B.S., Predoctoral Graduate Student (1985-1993)
Training: Quantitative and molecular genetics. Dissertation Topic: Genetics of Nicotine Acetylcholine Receptor.

Past Trainees

Sean Yutzy, M.D., Postdoctoral Fellow, (1990-1992)
Training: Nosology of somatoform and personality disorders
Currently: Assistant Professor of Psychiatry, Washington University School of Medicine

Dragan M. Svrakic, M.D., Ph.D., Fulbright Scholar from University of Belgrade, Yugoslavia (Sept 88-Aug 89)
Training: Collaboration on Cross-cultural studies of personality assessment and structure.
Currently, Assistant Professor of Psychiatry, Washington University School of Medicine

Stephen Dinwiddie, M.D., Postdoctoral Fellow (1987-1990)
Training: Clinical and genetic methods for studying neuroadaptive processes in substance abusers.
Currently: Assistant Professor of Psychiatry, Washington University School of Medicine

Ronald Martin, M.D., Psychiatry Resident, 1975-1977
Training: Supervised his follow-up of female felons I had previously studied; trained in conduct and analysis of longitudinal clinical studies
Currently: Professor & Chairman of Psychiatry, University of Kansas at Wichita.

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Collins E. Lewis, M.D., M.P.H., Psychiatry Resident, 1975-1977
Training: Supervised clinical and family study of alcoholics; trained in epidemiological methods and family studies.
Currently: Associate Professor of Psychiatry, Washington University.

William Coryell, M.D., Psychiatry Resident, 1977
Training: Supervised his participation in a reliability study of a new structured interview; trained in methods for conducting and interpreting reliability studies.
Currently: Professor of Psychiatry, University of Iowa.

John P. Rice, Ph.D., Postdoctoral Fellow, 1975-1977
Training: Directed reading about psychiatric genetics and genetic epidemiology; we jointly worked on extending methods for cultural inheritance and segregation analysis.
Currently: Professor of Psychiatry & Biostatistics, Washington University.

Andrew Scallet, Ph.D., Predoctoral Psychology Student, 1975-1976
Training: Supervised research on assessment and double-blind treatment studies of outpatients.
Currently: Research Psychologist, National Center for Toxicological Research, Jefferson, Arkansas

Lenore Teter, M.D., Psychiatry Resident, 1980
Training: Supervised research on psychiatric social adjustment of recent Russian immigrants.
Currently: Instructor in Psychiatry, Washington University, then private practice

Robert Desalle, B.S., Predoctoral Genetics Fellow, 1979
Training: Method of path analysis in studying inheritance of complex phenotype systems.
Currently: Completed dissertation in Genetics, Washington University.
Currently: Department of Biology, Yale University

Peter McGuffin, M.D., Postdoctoral Fellow, 1980-1981
Training: Advanced methods of genetic epidemiology including segregation, path, admixture, and linkage analysis.
Currently: Professor & Chairman of Psychiatry, Cardiff, England

Paul Van Eerdewegh, Ph.D., Predoctoral Fellow, 1980-1982
Training: Studies of statistical properties of copaths and selection in multivariate systems relevant in quantitative genetics.
Currently: Assistant Professor in Psychiatry in Genetic Epidemiology, Washington University.

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Dennis O'Rourke, Ph.D., Postdoctoral Fellow, 1980-1983
Training: Advanced methods of genetic epidemiology including segregation, path, and linkage analysis.
Currently: Professor of Anthropology, University of Utah.

Anne-Liss von Knorring, M.D., Postdoctoral Fellow, 1982-1983.
Training: Methods of genetic epidemiology relevant to adoption studies.
Currently: Professor of Child Psychiatry, University of Uppsala, Sweden.

Soren Sigvardsson, D. Med. Sci., Predoctoral Fellow, 1981
Postdoctoral Fellow, 1983
Training: Methods of genetic epidemiology and multivariate analysis relevant to adoption studies; longitudinal and cross-fostering studies of adoptees with relevance to child psychiatry.
Currently: Associate Professor of Child Psychiatry, Umea University.

Nancy J. Cox, Ph.D., Postdoctoral Fellow, 1982
Training: Advanced methods of genetic epidemiology for studying psychiatric disorders.
Currently: Assistant Professor, University of Chicago.

Eric Devor, Ph.D., Postdoctoral Fellow, 1982
Training: Advanced methods of genetic epidemiology in anthropology; population structure.
Currently: Assistant Professor of Psychiatry, University of Iowa, Iowa City

Mark Zoccolillo, M.D., Psychiatry Resident, 1983
Training: Supervised design and analysis of clinical and social comparison of matched groups of outpatients with somatoform and affective disorders; study of parenting and home environmental influences on children of outpatients.
Currently: Assistant Professor of Psychiatry, Texas Tech

Edward Lauterbach, M.D., Psychiatry Resident, 1984
Training: Design and analysis of psychiatric follow-up studies.
Currently: Associate Professor of Psychiatry, (Tenure) Mercer University School of Medicine, Macon, Georgia

Kara Forest, B.A., Biology Honors Student, 1986
Training: Etiology of anxiety states.
Currently: Medical school

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Wolfgang Baier, M.D., FRG Postdoctoral Fellow, 1987
Training: Genetic epidemiology of generalized minor seizures (collaborative project with Professor Doose at University of Kiel, FRG)
Currently: Child Neurologist, University of Kiel

David Craufurd, M.D., Wellcome Trust Fellow, 1987.
Training: Psychiatric Genetics.
Currently: Research Psychiatrist, St. Mary's Hospital, University of Manchester, England.

Sheila B. Gilligan, B.S., Predoctoral Graduate Student (1983-1988)
Training: Quantitative genetics of common diseases.
Dissertation Topic: Genetic and Phenotypic Heterogeneity in Alcoholism (scheduled to complete Spring, 1988).
Currently: Postdoctoral Fellow in Human Genetics, Medical College of Virginia (Dr. Andrew Heath), then Peace Corps in Africa.

Vicky Ryan, Undergraduate biology honors student (1987-1988)
Training: Techniques in family studies of alcoholism.
Currently: Medical School, University of Missouri

David L. Garver, M.D., Sabbatical Leave from University of Cincinnati, Depts. of Psychiatry and Pharmacology (Sept 88-Aug 89)
Training: Psychiatric genetics including clinical and molecular aspects.
Currently: Professor of Psychiatry, Southwestern Medical School, Dallas, Texas

Harald and Gabrielle Aschauer, M.D., Medical Research Council of Austria Fellows
Training: Neuropsychopharmacologist/psychiatrist coming for training in genetics of schizophrenia (Sept 87-March 1989).
Currently: Assistant Professors in Vienna

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Bibliography

Articles - 1970

1. Cloninger CR and Guze SB: Psychiatric Illness and Female Criminality: The Role of Sociopathy and Hysteria in the Antisocial Women. Amer. J. Psychiat., 127(3):303-311, 1970.

2. Cloninger CR and Guze SB: Female Criminals: Their Personal, Familial, and Social Backgrounds (The Relations of These to the Diagnoses of Sociopathy and Hysteria). Arch. Gen. Psychiat., 23:554-558, 1970.

Articles - 1973

3. Cloninger CR and Guze SB: Psychiatric Illness in the Families of Female Criminals: A Study of 288 First-Degree Relatives. Brit. J. Psychiat., 122:697-703, 1973.

4. Cloninger CR and Guze SB: Psychiatric Disorders and Criminal Recidivism: A Follow-up Study of Female Criminals. Arch. Gen. Psychiat., 29:266-269, 1973.

Articles - 1974

5. Hearst ED, Cloninger CR, Crews EL, and Cadoret RJ: Electrosleep Therapy: A Double Blind Trial. Arch. Gen. Psychiat., 30:463-466, 1974.

6. Cloninger CR: Group Rape: A Commentary. Med. Aspects of Human Sexuality, 8:81, 1974.

7. Cloninger CR, Packman PM, Cicero TJ, Boshans RL, and Robins E: Morphine Dependence and Enzyme Activity in the Hypothamus. Biochem. Pharmacol. 23:983-988, 1974.

Articles - 1975

8. Cloninger CR and Guze SB: Hysteria and Parental Psychiatric Illness. Presented at the Annual Meeting of APA, 1973. Psychol. Med., 5:27-31, 1975.

9. Reich T, Cloninger CR, and Guze SB: The Multifactorial Model of Disease Transmission: I. Description of the Model and its Use in Psychiatry. Brit. J. Psychiatry, 127:1-10, 1975. (Science Citation Index Citation Classic)

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CHAPTER 2

Epidemiology and Axis I Comorbidity of Antisocial Personality

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Antisocial personality is the only personality disorder that has been extensively studied in large-scale epidemiological surveys such as the Epidemiologic Catchment Area (ECA) project (Robins & Regier, 1991). It was included in the ECA because it could be reliably assessed using the Diagnostic Interview Schedule and ECA results could be compared with a substantial body of previous work (Robins, Tipp, & Przybeck, 1991). Persons with antisocial personality disorder (ASPD) are impulsive, aggressive, and aloof and are thought to have reduced capacities for work, love, guilt, and cooperation with authority figures. They have been studied in the general population (Robins et al., 1991), prospective longitudinal studies of child psychiatric patients (Robins, 1966) and adult felons (Goodwin & Guze, 1984), families of psychiatric patients and felons (Cloninger, Reich, & Guze, 1975a, 1975b), and adoptees (Crowe, 1972; Schulsinger, 1972).

Basic conclusions about the onset and course of ASPD have been inferred from prior longitudinal research. Antisocial personality disorder begins in childhood with behavior problems at home and school (Robins, 1966). It is five to seven times more common in males than females (Cloninger et al., 1975a; Sigvardsson, Cloninger, Bohman, & von Knorring, 1982). Consequently, data about ASPD are predominantly about men, but descriptive, longitudinal, and family studies have been carried out in women (Cloninger & Guze, 1970a, 1970b, 1973a, 1973b; Martin, Cloninger, Guze, & Clayton, 1985). Regardless of gender, the number and severity of indicators of antisocial conduct in childhood predict the probability of persistence into adulthood (Robins, 1978). Antisocial personality disorder continues throughout life in most cases but often becomes less problematic in middle or old age. More than a third of people with ASPD settle down and mature substantially by 50 years of age; they improve in their capacity for work and empathy, are better able to avoid serious legal problems, but usually remain impulsive, irritable, and aloof. Their maturation is most often delayed to their 30s but can occur at any age (Robins, 1966).

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Major descriptive characteristics of ASPD, including its diagnostic features and other psychiatric syndromes that often cooccur in the same individual, have been based on clinical and family studies (Cloninger & Guze, 1970a, 1973a). The disorder is characterized by repeated antisocial behavior in a wide range of personal and social contexts. In childhood, impulsive-aggressive behavior is most prominent. This includes fighting, cruelty to animals and other people, fire setting, running away from home, and disrespect for rules at home and school leading to a wide variety of disciplinary problems and conflict with authority figures. In adulthood, the impulsive-aggressive features persist and are associated with impairment in work and empathic social relations. People with antisocial personality disorder usually change jobs repeatedly because they are fired or quit. When they marry or cohabit, they usually have frequent conflicts leading to abuse, infidelity, desertion, separation, or divorce. About half have felony convictions or multiple arrests for serious criminal activity other than traffic violations (Robins et al., 1991).

Individuals with ASPD also are frequently alcohol or drug abusers (Lewis, Helzer, Cloninger, Croughan, & Whitman, 1982; Robins et al., 1991). Women especially have an increased risk of somatization disorder (Cloninger & Guze, 1970a; Cloninger et al., 1975b). Such individuals have been reported to be at either increased (Robins et al., 1991b) or decreased (Cleckley, 1964) risk of mood and anxiety disorders, suggesting the possibility of psychosocial heterogeneity that is not well distinguished by current behavioral criteria.

Antisocial personality disorder, substance abuse, and somatization often are observed in genetic relatives of people with criminality or broadly defined ASPD, whether or not they are reared together (Cloninger et al., 1975b; Bohman, Cloninger, von Knorring, & Sigvardsson, 1984). The importance of biogenetic factors in the development of ASPD also is supported by the fact that it has been recognized in every era and type of society, regardless of political or economic system (Robins et al., 1991). However, low socioeconomic status and inconsistent discipline in the early rearing environment increase the risk of developing the disorder (Bohman et al., 1984; Cloninger, Sigvardsson, Bohman, & von Knorring, 1982).

Despite the wealth of available information, the most funda-

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mental questions about ASPD remain unanswered. Is it a discrete category of illness, an extreme variant of one or more quantitative dimensions, or a pejorative label for nonconformists? What is its overlap with other personality disorders and psychiatric syndromes? What are the most promising ways for prevention and intervention with antisocial personality disorder? Is heterogeneity in course and comorbidity explained by individual differences in quantifiable components of personality? Here, we attempt to elucidate these basic questions by focusing on whether heterogeneity in the course and comorbidity of ASPD in the general population is explained by individual differences in quantifiable components of personality and psychopathology that have not been controlled for in earlier research.

THEORETICAL CONTEXT AND CONTROVERSIAL ISSUES

The limitations of prior work primarily are a consequence of problems in ascertainment and assessment of personality disorders. Current diagnostic criteria for personality disorders involve rather long checklists of many overlapping diagnostic features (American Psychiatric Association, 1994). Structured interviews for personality disorders are reliable but produce many overlapping diagnoses and take over 90 minutes to complete (Cloninger, Svrakic, & Przybeck, 1993; D. M. Svrakic, Whitehead, Przybeck, & Cloninger, 1993). Such interview methods are impractical for large-scale epidemiological research, which consequently has been limited to studies of one personality disorder (like the ECA) or to samples of treated cases. Treated cases may be unrepresentative for several reasons. In general, treatment samples overrepresent cases that are severely impaired, with multiple psychiatric syndromes, suggesting spurious associations (Berkson, 1946). In particular, treated cases may be unrepresentative of people with antisocial personalities, who seldom see themselves as the cause of their problems.

As a result of the limited assessment procedures available in the past, no data have compared antisocial personality disorder with other personality variants in the same sample of the general population. Recently, however, reliable and brief self-report questionnaires have been shown to distinguish subtypes of personality disorder (Cloninger et al., 1993; Livesley, 1987; D. M. Svrakic et al., 1993; Trull, 1992). Nearly all of this work has been conducted in nonclinical samples with few definite cases of personality disorder (Livesley, 1987; Trull, 1992). One instrument, however, the Temperament and Character Inventory (TCI), has been validated independently for differential diagnosis of personality disorders in both clinical and nonclinical samples (Cloninger, Przybeck, Svrakic, & Wetzel, 1994; Goldman, Skodal, McGrath, & Oldham, 1994; D. M. Svrakic et al., 1993). The validity of the TCI for differential diagnosis allows for efficient study of several controversial questions about ASPD.

The TCI distinguishes temperament traits, which are moderately heritable and stable throughout life, and character traits, which are weakly heritable, moderately influenced by social learning, and mature in a stagelike manner (Cloninger et al., 1993). *Temperament* refers to individual differences in basic emotional responses, such as anger, fear, and disgust. *Character* refers to individual differences in goals, values, and self-conscious emotions such as capacity for shame, guilt, and empathy. For example, ASPD is distinguished from other personality disorders by a unique profile of three temperament traits: high Novelty Seeking (i.e., impulsive, quick tempered), low Harm Avoidance (i.e., risk taking, fearless), and low Reward Dependence (i.e., aloof, independent). Other personality disorders can be distinguished by different profiles of high and low scores on these dimensions (Cloninger, 1987a; Goldman et al., 1994; D. M. Svrakic et al., 1993). In contrast, all types of personality disorder are characterized by immature character development. All cases of personality disorder are characterized by reduced ability to work and love. In other words, individuals who have a personality disorder are low in the TCI character dimension of Self-directedness: They are irresponsible, aimless, inept, low in self-esteem, and undisciplined. Many are also low in the TCI dimension of Cooperativeness: They are socially intolerant, lacking in empathy, selfish, revengeful, and unprincipled.

Consequently, the presence of any personality disorder can be detected by low scores on TCI character dimensions of Self-directedness and Cooperativeness. Different subtypes of personality disorder can be distinguished by their profile of temperament traits. Extreme temperament profiles, however, do not necessarily indicate a personality disorder, because they may be associated with mature character development. Thus, the combination of temperament and character defines the total personality, which may be either a mature personality or a personality disorder.

Substantial evidence supports the validity of diagnosing ASPD using the TCI. Discriminant validity has been demonstrated by its efficacy for differential diagnosis of personality disorders in several independent studies of psychiatric inpatients and outpatients (Cloninger et al., 1994; Goldman et al., 1994; D. M. Svrakic et al., 1993). Childhood and adolescent reports of the temperament profile of high Novelty Seeking, low Harm Avoidance, and low Reward Dependence are predictive of later antisocial conduct and substance abuse (Sigvardsson, Bohman, & Cloninger, 1987; Tremblay, Pihl, Vitaro, & Dobkin, 1994; Wills, Vaccaro, & McNamara, 1994). A sample of 223 criminals took Hare's Psychopathy Checklist and TCI temperament measures (Joseph Newman, personal communication, 1994, in Cloninger et al., 1994; see Newman, Chapter 30, this volume; Hart & Hare, Chapter 3, this volume). Factor 1 of the Psychopathy Checklist (PCL) measures core features of "primary" psychopathy, such as those described by Cleckley (1964), including superficial charm, habitual lying, and callous social detachment. This primary psychopathy factor of the PCL was correlated with the antisocial profile of high Novelty Seeking ($r = .26$), low Harm Avoidance ($r = -.10$), and low Reward Dependence ($r = -.24$). Factor 2 of the PCL measures "secondary" psychopathy or chronically unstable antisocial conduct. The unstable conduct factor corresponded to the explosive or borderline profile of high Novelty Seeking ($r = .45$), high Harm Avoidance ($r = .09$), and low Reward Dependence ($r = -.35$). In classifications antedating *DSM-III*, the first PCL factor corresponds to psychopaths who have a reduced ability to avoid punishment and to perform well on tasks mediated by fear and anxiety; in other words, primary psychopathy or PCL Factor 1 is

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associated with low TCI Harm Avoidance and high TCI Novelty Seeking. On the other hand, secondary psychopaths, who are neurotically unstable because of approach-avoidance conflicts about novelty, correspond to PCL Factor 2, which is associated with high TCI Harm Avoidance and high TCI Novelty Seeking. In more recent clinical work, secondary psychopaths usually would be diagnosed as having borderline personality disorder, which is characterized by the explosive temperament profile (Cloninger et al., 1994; also see Zanarini & Gunderson, Chapter 8, this volume). Secondary psychopathy overlaps extensively with chronic criminality and impulsive personality disorders in general.

Differential diagnosis of multiple personality disorders that share some features with antisocial personality disorder allows comparison of their course and clinical correlates. For example, cases with borderline and histrionic personality disorders according to *DSM-IV* are impulsive and aggressive, like those with ASPD, but differ in other traits, such as high Harm Avoidance (i.e., anxiety proneness, as in people with borderline personality disorder) or high Reward Dependence (i.e., social warmth, as in those with a histrionic personality). It is necessary to distinguish such subtypes of personality disorder to compare their epidemiology and comorbidity for such variables as differential risks for suicide attempts, alcoholism, and depression. Prior studies of antisocial psychiatric patients have reported a high risk of suicide and suicide attempts, whereas studies of antisocial personality disorder carried out in the criminal justice system report little suicidal behavior, even in studies by the same investigators (Goodwin & Guze, 1984; Martin et al., 1985). Resolution of these inconsistencies requires comprehensive assessments of personality and psychopathology in general population samples.

Furthermore, heterogeneity in the course of illness and comorbidity may depend on differences in overall severity or differences in specific components of personality. Consequently, it is crucial to have a reliable means of the quantifying severity of different components of personality. For example, people with ASPD show fewer social problems with advancing age but often remain impulsive and adventurous (Robins, 1966). This suggests that some components of antisocial personality disorder may improve more with age than others. In particular, Novelty Seeking decreases with age by approximately 18%, so that older individuals become noticeably less impulsive (more reflective), less rule breaking (more orderly), and less quick tempered (more stoical). Cooperativeness increases markedly in most children during school age and then increases slightly (by 12%, on average) after age 18; the development of Cooperativeness appears to be particularly impaired in those with antisocial and borderline personalities (D. M. Svrakic et al., 1993). Self-directedness increases markedly in most people during adolescence and young adulthood and then increases only slightly (on average, by 9%) after age 18. Of course, the practical significance of such changes depends on the extent of change in each case and the extent of the initial deviation.

In summary, to distinguish ASPD from other normal and abnormal personality variants, two kinds of data are needed that have not been available previously. First, the demographic and clinical correlates of antisocial personality disorder must be compared with those of other types of personality disorder in a general population. In addition, people with antisocial personality disorder should be compared with people who have extreme temperaments but are mature in character.

We attempted to do this by studying a stratified random sample of 1,000 noninstitutionalized adults, 18 years of age or older, who lived in the greater metropolitan area of St. Louis, Missouri. Potential participants initially were identified at random from standard telephone lists and asked if they were willing to participate in a questionnaire survey of personality and health sponsored by the National Institutes of Health and Washington University School of Medicine. Of 1,740 individuals solicited for possible participation, 243 declined (14% refusal). From the 1,497 volunteers, a final panel of 1,000 was accepted into demographic strata in numbers representative of the 1990 federal census according to age (18–34, 35–54, 55+), gender (male, female), ethnicity (White, Black, Hispanic, other), and geographical location of household (six counties). The 1,000 selected participants were mailed a questionnaire along with prepayment of $5 and paid another $20 on return of the completed questionnaire. Those who did not return the questionnaire after a few weeks were reminded with postcards and later phone calls. Altogether 866 subjects returned the questionnaire. Of these 804 were nearly complete and valid based on internal consistency checks built into the questionnaire to detect careless or inconsistent responding. Four additional cases are excluded because of some missing values.

The 800 complete and valid respondents included slightly more women than expected (56.9% observed vs. 52.0% expected) but were otherwise representative of the general population demographically. The respondents also were representative of the general population in terms of their personality and alcohol history, as assessed in a national area probability sample conducted as part of the 1987 General Social Survey for the National Science Foundation (Cloninger, Przybeck, & Svrakic, 1991). Data shown later indicate that the prevalences of psychiatric disorders and quantitative scale scores for other measures of psychopathology in this population are similar to those obtained in the ECA, a large multisite epidemiological survey using structured psychiatric interviews (Robins & Regier, 1991) and other community surveys using interviews and questionnaires (Myers & Weissman, 1980).

Assessment Questionnaires

Subjects completed a questionnaire booklet with separate sections for general demographic information, the TCI (Cloninger et al., 1994); the Inventory of Personal Characteristics (Waller & Zavala, 1993); the short Michigan Alcoholism Screening Test (SMAST; Selzer, Vinokur, & van Rooijen, 1975); the NIMH Center for Epidemiological Studies depression scale (CES-D; Radloff, 1977); the Medical Outcome Study (MOS) short-form General Health Survey (Stewart, Hays, & Ware, 1988), which includes the five-item Mental Health Inventory (MHI-5; Berwick et al., 1991); and additional questions described later about psychopathology and mental health treatment. The questionnaire was estimated to take about 75 minutes to complete on average. In a 12-month follow-up examination, the test-retest reliability of the personality ratings was high (i.e., correlations of .78 to .85 for each of the TCI dimensions), which supports the reliability and validity of the self-reports.

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Measures of Psychopathology

The degree of character maturity was measured as the sum of TCI scores for Self-directedness and Cooperativeness, which measure the certainty and severity of personality disorder (D. M. Svrakic et al., 1993). A diagnosis of definite personality disorder was made in 141 individuals (17.6%), as shown in Table 2.1, which is about the bottom sixth of the population in character maturity. Subtypes of personality disorders and temperament types were specified as described in detail elsewhere (Cloninger, 1987a; D. M. Svrakic et al., 1993). Individuals were rated as high or low on a temperament dimension according to median splits. For example, people with antisocial personality disorder were those with definite personality disorder and an adventurous temperament profile (i.e., high Novelty Seeking, low Harm Avoidance, low Reward Dependence). Those with borderline personality disorder were those with definite personality disorder and an explosive temperament (i.e., high Novelty Seeking, high Harm Avoidance, and low Reward Dependence). Other erratic or impulsive personality disorders (Cluster B) were the others with high Novelty Seeking. Other definite personality disorders (nonimpulsive cases in Clusters A and C) were characterized by low Novelty Seeking. Other possible personality disorders were those in the second sextile of the population in maturity, as shown in Table 2.1. Mature types include those who were average or higher in maturity in Table 2.1 and were subdivided according to temperament type.

Measures of psychopathology from the SMAST, CES-D, and MHI-5 were based on other clinical validation studies in which both questionnaires and interview diagnoses were completed independently. The CES-D asks about 20 depressive symptoms, which are rated on a 4-point frequency scale for the past week. In a community sample, a CES-D score of 21 or higher had a sensitivity (i.e., proportion of true cases detected) of 54% and a specificity (i.e., proportion of noncases correctly classified) of 96% for major depression diagnosed by structured interview; scores of 16 or higher had a sensitivity of 64% and a specificity of 94% (Myers & Weissman, 1980). The MHI-5 has five items about anxiety and depression rated on a 6-point frequency scale; scores of 17 or higher reliably indicate the presence of clinically significant anxiety or mood disorder (Berwick et al., 1991). In this sample, scores on the CES-D and MHI-5 were highly correlated ($r = .77$, $p < .001$). Therefore, these scales are useful for indicating the severity of anxiety and depression and screening for anxiety and depressive disorders, but not for distinguishing among specific categories of mood and anxiety disorders.

The use of self-report questionnaires has both strengths and limitations compared to interviews. Self-reports are inexpensive and practical for large-scale surveys. They eliminate observer bias and allow detailed analysis of psychometric properties of the instruments. Nevertheless, the CES-D and MHI-5 indicators do not distinguish well among different categories of mood and anxiety disorders. They do, however, reliably indicate the presence of any mood or anxiety disorder and the severity of anxiety and depression symptom levels (Berwick et al., 1991).

CURRENT FINDINGS ABOUT DEMOGRAPHIC PATTERNS

The relationship of temperament type to degree of character maturity was evaluated as a preliminary check on the prevalence of different types of personality disorder. Table 2.1 shows that 26 (27%) of the 98 individuals with adventurous temperaments had definite personality disorders using the TCI criterion calibrated to correspond to *DSM-IV* thresholds. The only temperament type with a

TABLE 2.1 Degree of Character Maturity for Each Type of Temperament, Rated Using the Temperament and Character Inventory in a General Adult Population (1994 St. Louis Health Survey)[a]

		Degree of Character Maturity			
		Personality Disorder		No Personality Disorder	
Temperament Type	Number of Subjects	Definite (row %)	Possible (row %)	Average (row %)	Mature (row %)
Adventurous (Nhr)	98	27	12	32	30
Explosive (NHr)	76	49	20	25	7
Dramatic (NhR)	134	4	10	39	47
Independent (nhr)	97	7	11	40	41
Sensitive (NHR)	100	27	19	38	16
Methodical (nHr)	147	22	30	33	15
Reliable (nhR)	79	1	6	30	62
Cautious (nHR)	69	7	16	36	41
Column total number	800	($n = 141$)	($n = 131$)	($n = 276$)	($n = 252$)
Row % of total		17.6%	16.4%	34.5%	31.5%

[a]Maturity of character was measured by the sum of TCI Self-directedness and Cooperativeness and divided into lowest sixth (definite PD), second lowest sixth (possible PD), middle third (average), and highest third (mature). Temperament type was measured by the configuration of three dimensions divided by median splits: Novelty Seeking high (N) or low (n), Harm Avoidance high (H) or low (h), and Reward Dependence high (R) or low (r).

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TABLE 2.2 Prevalence Estimates of Antisocial Personality Disorder (ASPD) in the St. Louis Health Survey (SLHS) and the Epidemiologic Catchment Area (ECA) Study (all sites)

Population	Prevalence of ASPD		
	SLHS		ECA
	f/N	%	%
Total	26/800	3.3	2.6
Gender			
Males	22/345	6.4	4.5
Females	4/455	0.9	0.8
Race			
Whites	18/652	2.8	2.6
Blacks	6/125	4.8	2.3
Age			
18–29	15/178	8.4	3.8
30–44	7/274	2.6	3.7
45–64	3/216	1.4	1.4
65+	1/131	0.8	0.3

higher proportion (49%) of definite personality disorder was the explosive type associated with borderline personality disorder.

Gender, Race, and Age

Using this TCI classification procedure for definite personality disorder provided an estimate of the prevalence of antisocial personality disorder in the general population of the St. Louis Health Survey (SLHS), 3.3%, in approximate agreement with that obtained using the Diagnostic Interview Schedule in the ECA study, namely, 2.6% (Table 2.2). Likewise, young men were most likely to be diagnosed as having antisocial personality disorder in both studies. The slight excess of ASPD in Blacks was not statistically significant in the SLHS and was not observed in the ECA. In both studies gender and age had strong impacts.

A more complete account of the prevalence of antisocial personality disorder and other personality variants by gender and age is shown in Table 2.3. Antisocial personality disorder shows a greater predominance of men and individuals under age 30 than any other personality disorder or temperament type. There is a sevenfold excess of men with ASPD, compared to a twofold excess of men with borderline personality disorder and a slight excess of women with other impulsive personalities (e.g., histrionic or narcissistic personality). Likewise, among mature temperament types, there is a twofold excess of men with adventurous temperaments in contrast to the excess of women with other types.

Because 22 of the 26 individuals with antisocial personality disorder were men, the prevalence of ASPD and other personality variants was examined by age in men only. With women excluded, it remains clear that all the impulsive personality disorders (antisocial, borderline, and other) are less prevalent in older age cohorts, whereas nonimpulsive personality disorders are slightly more frequent in older cohorts, increasing from 7% in those under 30 years to 10% in those over 65 years of age. This supports the suggestion in *DSM-IV* that impulsive (Cluster B) disorders are more likely than nonimpulsive (Clusters A and C) disorders to improve with age (APA, 1994). This prognostic difference may be explained partly by the decrease in Novelty Seeking with increasing age, as noted earlier, or partly by the possibility that individuals high in Novelty Seeking may have earlier mortality. In fact, the proportion of individuals who have any personality disorder is lower in older cohorts (under 40%) than in those under age 30 (over 60%). In positive terms, 39% of those under 30 years of age are mature (i.e., higher than the bottom third in Self-directedness and Cooperativeness) compared to 60% or more of those age 30 years or older. The association between character maturity and age occurs in both adventurous and other temperaments.

Education

Antisocial personality disorder has often been associated with low educational achievement, particularly failure to graduate from high school (Robins et al., 1991). This association is confounded partly by disciplinary problems in school being part of the diagnostic criteria. In the SLHS, it is possible to examine the association with educational level without this confound (Table 2.4). Borderline person-

TABLE 2.3 Prevalence of ASPD and Other Personality Variants by Gender and Age in the SLHS

Group	Gender (%)		Age (%)			
	Male (n = 345)	Female (n = 455)	18–29 (n = 178)	30–44 (n = 274)	45–64 (n = 216)	65+ (n = 131)
Personality Disorders						
Antisocial	6.4	0.9	8.4	2.6	1.4	0.8
Borderline	6.4	3.3	7.9	4.4	4.6	0.8
Other Impulsive	3.8	4.2	5.6	3.7	4.6	1.5
Not Impulsive	7.5	4.4	5.6	6.2	3.7	8.4
Any Possible	17.7	15.4	20.8	15.7	12.0	19.1
Mature Types						
Adventurous	10.7	5.1	6.7	8.4	8.3	5.3
Other	47.5	66.8	44.9	59.1	65.3	64.1
Total	100.0	100.0	100.0	100.0	100.0	100.0

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TABLE 2.4 Education and Employment by Personality Type in SLHS

Personality Type	Number of Subjects	Years of Education[a] < 12 (row %)	12 (row %)	13+ (row %)	Employment Status[b] No Job (row %)	Part-Time (row %)	Full-Time (row %)
Personality Disorders							
Antisocial	26	8	38	54	0	12	65
Borderline	37	30	27	43	11	22	46
Other Impulsive	32	13	37	50	3	22	66
Not Impulsive	46	15	26	59	7	7	52
Any Possible	131	15	37	48	7	12	45
Mature Types							
Adventurous	60	3	10	87	7	13	55
Other	468	11	29	59	3	11	50
Total	800	12	30	58	5	12	51

[a]Not high school graduate (<12 yrs), high school graduate (12), 1–3 years of college (13–15 yrs), and 4 or more years college (16+).
[b]Employment status distinguished part-time paid employment, full-time paid employment, students/housemakers, retired, and no job (and none of preceding). The retired and student/homemakers not shown here.

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ality disorder is associated with failure to graduate from high school (30% in people with borderline personality disorder vs. 12% in others), but antisocial personality disorder is not (8%). Furthermore, mature adventurous individuals are actually most likely to graduate from high school (97% vs. 88%) and continue with some college education (87% vs. 58%).

Employment

It is well established that antisocial personality disorder leads to occupational instability, such as frequently quitting or being fired (Robins, 1966; Robins et al., 1991). This association is confounded partly by occupational instability being part of the diagnostic criteria. Consequently, it is interesting to evaluate the association, if any, of ASPD with current employment status when ASPD is diagnosed on the basis of personality traits alone and not employment history. Table 2.4 shows that underemployment (i.e., part-time or no job) is associated with borderline and other impulsive personality disorders but not with antisocial personality disorder. Those with ASPD are usually employed full time, although not necessarily at the same job. This suggests that prior reports of chronic unemployment with ASPD may be confounded by criteria that do not adequately distinguish ASPD from borderline personality disorder. An alternative hypothesis is that a chronically unemployed person with an antisocial personality disorder becomes anxious or depressed, which could inflate his or her Harm Avoidance score and lead to a change in diagnosis from antisocial to borderline personality. This alternative hypothesis is unlikely in most cases, however, because older cohorts have fewer people with both antisocial and borderline personality, not more. Accordingly, underemployment appears to be attributable largely to a borderline, not an antisocial, personality. The rate of unemployment in this sample (5%) is similar to that officially reported for this region at the time, suggesting that unemployed people were accurately represented in the SLHS sample.

Marital Status

The association of antisocial personality disorder with marital instability is well known from prior studies. In the SLHS, antisocial personality was most strongly associated with having never been married (46% vs. 18%). Those with ASPD are less likely to have ever married than other types of definite personality disorders (46% vs. 20% to 32%) and much less likely than mature adventurous (20%) or other nonadventurous (13%) personalities. These differences may be partly a function of the lower mean age of those with antisocial personality disorder, but it is also seen when the comparison is limited to people younger than 30. Among the 178 people under age 30, 73% of the 15 having an antisocial personality were never married, compared with 55% of the 163 others. Furthermore, temperament substantially influences the rate of being single in people under 30 years of age: 67% of the 12 mature adventurous people under age 30 had remained single, which is similar to the single rate in those with antisocial personality disorder. With the recent decreased social pressure to marry early, people with ASPD appear to be more likely to remain single until they are older and more mature, rather than to enter into unstable early marriages.

Religious Activity

People with antisocial personality disorder were less likely than any other personality group to say they were affiliated with any religion (30% vs. 10% unaffiliated). They also indicated the lowest frequency of attending church of any group. Individuals with any type of personality disorder attended church less often than those without personality disorders. Two thirds of those with antisocial and borderline personalities reported that they rarely or never attended church, whereas two thirds of those without personality disorder reported attending church at least monthly and one third without personality disorders attended at least weekly.

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CURRENT FINDINGS ABOUT HEALTH AND COMORBIDITY

In general, people with antisocial personality disorder report that their overall (mental and physical) health is very good (58%) but not excellent (12%). People with other types of personality disorders rate their overall health lower than very good more often than those with antisocial personality disorder (73% to 50% vs. 31%), whereas mature individuals more often rate their health excellent than those with antisocial personality disorder (26% vs. 12%). This confirms the general impression that people with antisocial personality disorder do not see themselves as ill.

Mental Health Treatment and Suicide Attempts

People with antisocial personality disorder do not report more mental health problems than others in general in the SLHS (Table 2.5). In contrast, people with borderline and nonimpulsive personality disorders are most likely to report problems, particularly psychiatric hospitalization and suicide attempts. Only 4% of those with antisocial personality disorder reported past suicide attempts compared to 30% of those with borderline personality disorder and 6% of the general population. Only 8% were ever hospitalized for their mental health compared with 22% of those with borderline personality disorder and 6% of the general population. Suicide attempts in men have often been associated with ASPD in psychiatric treatment samples; these data suggest that antisocial personality disorder is not well differentiated from borderline personality disorder when checklists of antisocial behavior are the basis for diagnosis. This hypothesis also is supported when comparisons are restricted to men.

Substance Abuse

Alcoholism often has been associated with antisocial personality disorder in past research (Cloninger, 1987b; Lewis et al., 1982; Robins et al., 1991), and this association is strongly confirmed in the SLHS (Table 2.6). The lifetime prevalence of definite alcoholism was estimated as 14.1% in the SLHS, which is similar to the prevalence of 13.8% in all ECA sites and 15.9% in St. Louis specifically (Robins & Regier, 1991). In contrast to these overall rates, 39% of those with ASPD in the SLHS were definite alcoholics and another 12% were possible alcoholics. The only other group with a similarly elevated prevalence of alcoholism was borderline personality, with a 43% prevalence. The rates are slightly higher in other personality disorders (15% to 19%) than in mature people (9% to 13%).

The motivational mechanisms associated with substance abuse were examined further with another legal substance, cigarettes. Antisocial personalities, like those with all personality disorders, are more likely to have ever smoked than people who are not adventurous and mature (77% vs. 62%). They are also more likely to still smoke recently (65% vs. 46%). Consequently, they also are much less likely to stop smoking. Taking frequency of smoking into account, individuals with any impulsive personality disorder are less likely to quit than all other personality types; for example, among those who have smoked a pack per day, only 10% of those with antisocial personality disorder, 25% of those with borderline personality disorder, and 22% of those with other impulsive personalities have quit, which is lower than any other group (35% to 45%). Among light smokers, the rates of quitting are higher overall, but the difference between antisocial and borderline personality disorders (60%) versus nonimpulsive (82%) and mature types (67% to 77%) also holds.

Despite starting more and quitting less, however, antisocial personalities are *not* more likely than mature people to smoke a pack of cigarettes daily. They have the lowest rate of ever having smoked a pack of cigarettes daily (50%) compared to all other groups (58% to 83%). In other words, they have a high rate of lifelong light smoking (20%) compared to all other personality types (7% to 14%). This is consistent with other findings that individuals with impulsive personality disorders use substances such as alcohol and cigarettes for pleasant stimulation and do not want to quit using them (Cloninger, 1987b; Cloninger, Sigvardsson, Przybeck, & Svrakic, 1995).

Depression and Anxiety

Prior research indicates that most patients with personality disorders are likely to have comorbid anxiety and depressive disorders (D. M. Svrakic et al., 1993), but that antisocial personality disorder may be relatively resistant to anticipatory anxiety, depression, and guilt

TABLE 2.5 Indicators of Lifetime Mental Health Function by Personality Type in SLHS

Personality Type	Number of Subjects	Mental Health Treatment: Nerve Meds? (row %)	Psych Outpt? (row %)	Psych Inpt? (row %)	Attempt Suicide? (row %)
Personality Disorders					
Antisocial	26	15	15	8	4
Borderline	37	35	46	22	30
Other Impulsive	32	41	28	6	9
Not Impulsive	46	30	35	17	20
Any Possible	131	35	23	8	8
Mature Types					
Adventurous	60	13	15	7	5
Other	468	27	19	3	3
Total	800	28.2	21.5	6.4	6.4

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TABLE 2.6 Prevalence of Definite Alcoholism, Definite Depression, and Multiple Somatic Complaints[a] by Personality Type in the SLHS

		Multiple Somatic Complaints				
Personality Type	Number of Subjects	Definite Alcoholic (row %)	Definite Depressed (row %)	4+ Bodily Pains (row %)	2+ GI Symptoms (row %)	Both Pains + GI (row %)
Personality Disorders						
Antisocial	26	38	8	12	4	0
Borderline	37	43	46	32	32	14
Other Impulsive	32	19	50	6	25	3
Not Impulsive	46	15	54	15	28	9
Any Possible	131	17	30	10	21	5
Mature Types						
Adventurous	60	13	7	2	15	0
Other	468	9	6	7	14	3
Totals	800	14	17	9	17	4

[a]Alcoholism based on SMAST; depression definite with CES-D score of 21 or more; four or more bodily pains and two or more GI complaints as seen in irritable bowel syndrome are characteristic of somatization disorder.

(Cleckley, 1964; Hare, 1978). Both of these observations were supported by findings about anxiety and depressive symptoms in the SLHS. The prevalence of definite depression according to the CES-D scale was about 8% in those with antisocial personality disorder, which is similar to that in mature personality types (6% to 7%) and much lower than in other personality disorders (46% to 54%). Likewise, using a more restrictive criterion for anxiety and depressive disorders based on the MHI-5, 4% of those with ASPD were ill, which is about the same as in mature individuals and much lower than in those with other personality disorders (31% to 46%). The rate of anxiety disorders in ASPD was lower than in all others both for cases with (0% vs. 4%) or without (4% vs. 8%) a history of panic attacks. The lifetime prevalence of either specific (23% vs. 25%) or social (19% vs. 18%) phobias was about the same in those with antisocial personality disorder as in mature people and about half that in those with other types of personality disorder (35% to 49% specific phobias and 25% to 57% social phobias).

Somatization

In contrast with the relative resistance to anticipatory worrying and anxiety in antisocial personality disorder, people with antisocial personality disorder are reportedly prone to multiple somatic complaints and, in some cases, somatization disorder (Cloninger & Guze, 1970a). Such somatization with little or no anticipatory anxiety may be associated with low tolerance for frustration and low endurance of pain in individuals with impulsive temperaments (Cloninger, 1988). Alternatively, somatization may be associated with immature character regardless of the temperament profile.

The diagnosis of somatization disorder in *DSM-IV* requires complaints of frequent pain in four or more body regions as well as two or more gastrointestinal symptoms, such as those reported in irritable bowel syndrome (Yutzy et al., 1995). Both the bodily pains and bowel complaints are necessary but not sufficient for the diagnosis of somatization disorder. Such complaints were evaluated in the SLHS, as summarized in Table 2.6. Multiple somatic complaints were more frequent in cases of personality disorder than in mature individuals. In particular, the risk of four or more bodily pains was 18% in definite PD, 10% in possible PD, 6% in average individuals, and 5% in the most mature third of individuals. Multiple bodily pains occurred in 12% of those with antisocial personality disorder and only 2% of mature adventurous individuals. The combination of multiple bodily pains and irritable bowel complaints was common in those with borderline personalities (14%) but not in those with antisocial personalities (0%). This is explained by the additional observation that high Harm Avoidance was significantly correlated ($p < .001$) with the number ($r = .35$) and frequency ($r = .37$) of bodily pains as well as with the number ($r = .29$) and frequency ($r = .34$) of irritable bowel complaints. Furthermore, both high Harm Avoidance and low Self-directedness contributed significantly to the prediction of the number and frequency of bodily pains and irritable bowel complaints in multiple regression analyses. Similar associations with personality occurred regardless of gender, but women had higher rates of somatic complaints overall. In summary, somatization appears to covary with anxiety-proneness (i.e., high Harm Avoidance) and immature character in general (i.e., low Self-directedness) rather than a specific temperament profile or personality disorder subtype.

CONCLUSIONS

The SLHS is the first study of the clinical and epidemiological correlates of antisocial personality disorder in a general population in which all types of temperament and character variation were systematically assessed. The findings of this study allow resolution of several controversial issues about the epidemiology and Axis I comorbidity of ASPD. It also suggests conclusions about the basic concept of personality disorder.

First, personality disorders are not discrete diseases but clini-

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cally distinct and relatively stable configurations of multiple quantitative traits. No sharp natural boundary between disorder and maturity has ever been demonstrated for any personality disorder. Rather, there is quantitative variation in degree of character maturity, and about the bottom sixth of the population are sufficiently immature that they are distinguished as having a personality disorder. This distinction is not completely arbitrary or artificial, however. Studies of longitudinal development show that antisocial personality disorder is a moderately stable configuration in a complex adaptive network (N. M. Svrakic, D. M. Svrakic, & Cloninger, 1996). The dynamic interactions among multiple correlated dimensions make the antisocial personality syndrome more stable than intermediate or mixed configurations (Cloninger et al., 1994). Such stable multidimensional configurations make prevention and treatment difficult but not impossible.

Second, antisocial personality disorder is primarily a disorder of young men. With increasing age, Novelty Seeking decreases and the character traits of Self-directedness and Cooperativeness increase. These changes lead to improvement or remission of ASPD in many cases, as has been previously documented in longitudinal studies.

Third, antisocial personality disorder should be distinguished from borderline personality disorder, although both are partly characterized by impulsivity (i.e., high Novelty Seeking) and social detachment (i.e., low Reward Dependence). Borderline personality disorder is strongly associated with failure to graduate from high school, underemployment, anxiety, depression, somatization, and suicide attempts. In contrast, the associations of antisocial personality disorder with these psychosocial problems is weak at most, in contrast to the conclusions of prior studies that did not distinguish antisocial and borderline personality disorders. These two disorders can be distinguished by variation in a single dimension of temperament: Harm Avoidance scores are low in antisocial personality disorder and high in borderline personality disorder. Consequently, borderline personality disorder is more likely to be associated with more severe immature character development and with fearful responses to stress, including anxiety, depression, and somatization. The distinction between antisocial and borderline personalities appears to correspond to the distinction between primary and secondary psychopathy in the older literature (Cleckley, 1964).

Fourth, all the impulsive personality disorders (antisocial, borderline, histrionic, and narcissistic) are at increased risk for substance abuse, including alcoholism, cigarette smoking, and illegal drug use. The association between substance abuse and impulsive personality disorders is caused both by more frequent initiation and less frequent cessation of substance abuse for pleasant stimulation.

Finally, the current results are consistent with prior observations, if it is accepted that behavioral checklists for antisocial personality disorder, such as that in *DSM-IV*, allow overlap between antisocial and borderline personality disorders. More generally, the interpretation of the current findings is clearer than in prior work because of the availability of appropriate comparison groups, including both immature and mature personality types, within the same sample. Identification of all these subgroups within a sample of the general population provides assurance against the selection artifacts that confound interpretation of associations in treatment samples.

FUTURE WORK

The current findings demonstrate the ease and utility of recent improvements in case finding for all types of personality disorder. It no longer should be necessary to limit the diagnosis of personality disorders in large-scale epidemiological projects to antisocial personality disorder, as was necessary in the ECA study. The current findings show how important it is to assess personality comprehensively and quantitatively in order to understand the epidemiology and comorbidity of any particular syndrome.

A major limitation of the SLHS and most prior work on antisocial personality disorder is the small number of women with ASPD who have been studied. Although the public health problem involves primarily men, these women represent an extreme and highly informative risk group (see Giordano & Cernkovich, Chapter 46, this volume). This calls for much larger samples than the SLHS. Samples of 5,000 to 10,000 from the general population would be needed to ascertain 130 to 260 men and 20 to 40 women with antisocial personality disorder.

A developmental perspective is needed to understand the psychosocial problems associated with antisocial personality disorder (N. M. Svrakic et al., 1996). Large-scale longitudinal studies of individuals and family members are required to characterize the dynamic interactions of the many factors that influence the development of ASPD from childhood throughout adulthood.

Finally, public concern for violence and underemployment should lead to research on both antisocial and borderline personality disorders. Now that self-report measures are available that are quantitative and reliable for the differential diagnosis of all personality disorders, such studies do not require unusual expense for clinical assessment.

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HANDBOOK OF ANTISOCIAL BEHAVIOR

Editors

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National Institute of Mental Health



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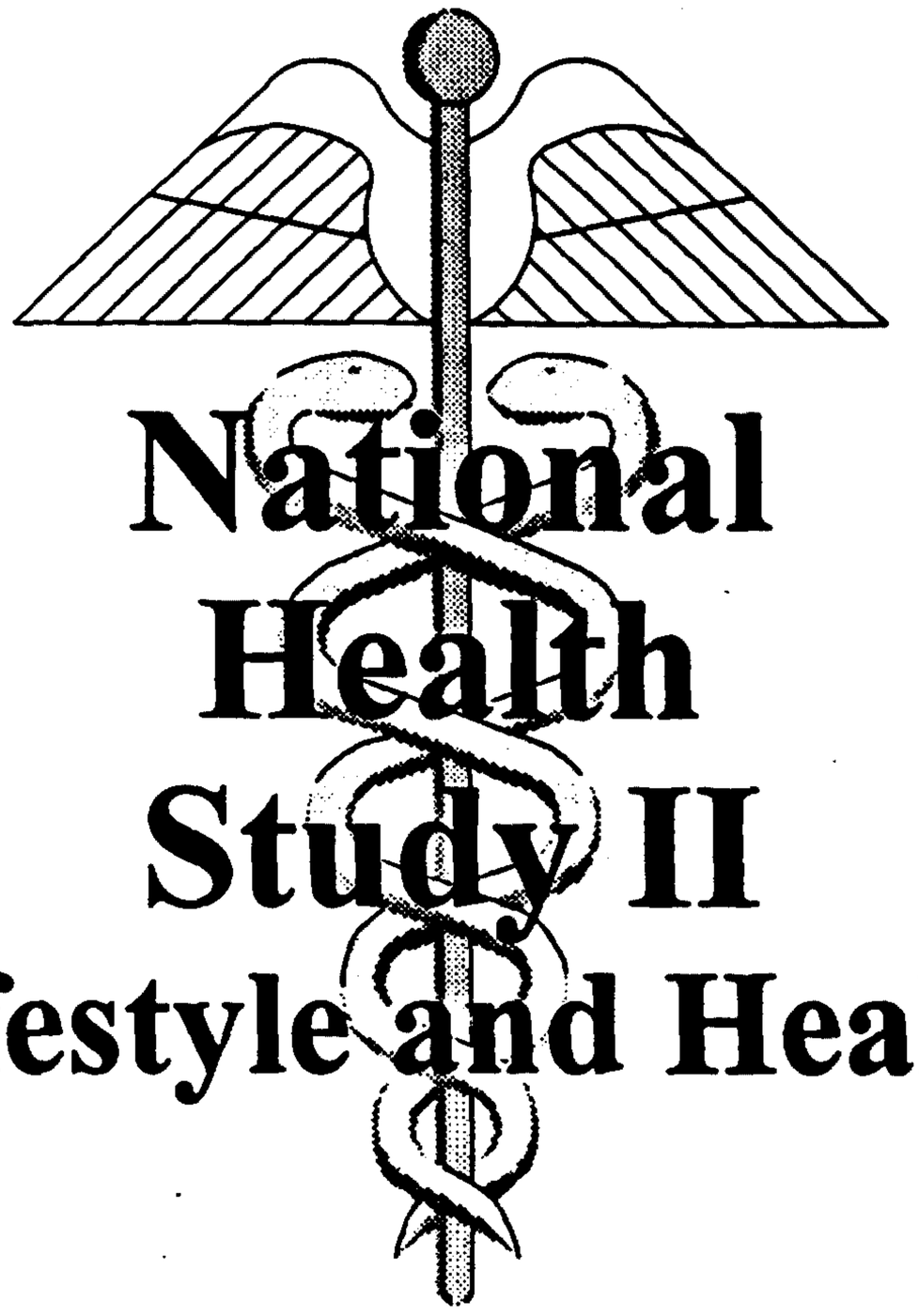
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National Health Study II
Lifestyle and Health

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EXHIBIT
5
11/13/97

FOR USE ONLY BY SCIENTIFICALLY SELECTED RESPONDENTS

Participation in this study is voluntary.

The information you provide will be treated as *Strictly Confidential.*

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Washington University
School of Medicine
4940 Children's Place
Box 8134
St. Louis, MO 63110

Contact: Cynthia A. Whitehead
(314) 362-7071

When you have completed the survey, please return it to Washington University School of Medicine in the enclosed, prepaid envelope. If you wish to deliver it personally, please call Cynthia Whitehead (362-7071) to arrange an appointment.

THANK YOU!

Washington
WASHINGTON·UNIVERSITY·IN·ST·LOUIS
School of Medicine

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GENERAL INFORMATION

This section asks for some general information which will be helpful as we compile the data from this study. Please fill in the information below. If you are not sure of an exact answer, please give your best estimate.

1. Today's date _____/___/___
Month/ Day/ Year

2. Your Sex (circle): Female Male

3. Ethnic Group (circle): Black White Hispanic Other_____
(Please specify)

4. Your Age: _____ Date of Birth: _____/___/___
Month/ Day/ Year

Place of birth: _____ _____ _____
City State Zip

5. Your current marital status (Please circle appropriate letter)

Never Married	Widowed	Married	Remarried	Living Together	Living Together (Gay)	Separated	Divorced
(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)

6. Your employment (Please circle appropriate letter):

Student	Homemaker	Unemployed	Part-time	Full-time	Retired
(A)	(B)	(C)	(D)	(E)	(F)

Thank you, now proceed to SECTION 1

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Section 1

General Health Information

1. In general, how would you describe your health? (Check only one number below.)

   _____ 1. Excellent
   _____ 2. Very Good
   _____ 3. Good
   _____ 4. Fair
   _____ 5. Poor

2. Thinking about your physical health, which includes physical illness and injury, for how many days during the last 30 days was your physical health <u>not good</u>?

   _____
   Number of Days

3. Thinking about your mental health, which includes stress, depression and problems with your emotions, for how many days during the last 30 days was your mental health <u>not good</u>?

   _____
   Number of Days

For each of the following questions, please circle the number that comes closest to the way you have been feeling <u>DURING THE PAST MONTH</u>. (Circle only one number on each line.)

1 None of the Time	2 A Little of the Time	3 Some of the Time	4 A Good Bit of the Time	5 Most of the Time	6 All of the Time

	1 None of the Time	2 A Little of the Time	3 Some of the Time	4 A Good Bit of the Time	5 Most of the Time	6 All of the Time
4. How much of the time, during the past month, has your health limited your social activities (like visiting with friends or close relatives)?	1	2	3	4	5	6
5. How much of the time, during the past month, have you been a very nervous person?	1	2	3	4	5	6
6. During the past month, how much of the time have you felt calm and peaceful?	1	2	3	4	5	6
7. How much of the time, during the past month, have you felt down-hearted and blue?	1	2	3	4	5	6
8. During the past month, how much of the time, have you been a happy person?	1	2	3	4	5	6
9. How often, during the past month, have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6

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Have you been told by a doctor, nurse, or other health professional that you have any of the following health problems?

1.	High blood pressure?	YES	NO
2.	High cholesterol level?	YES	NO
3.	Diabetes (sugar diabetes)?	YES	NO
4.	Problems with heart and blood circulation?	YES	NO
5.	Depression, anxiety, or emotional problems?	YES	NO
6.	Alcoholism or drug problems?	YES	NO
7.	Arthritis or rheumatism?	YES	NO
8.	Cancer?	YES	NO

In some families several people may have similar health problems. Has anyone in your immediate family (parents, children, brothers or sisters) had any of the following problems?

1.	High blood pressure?	YES	NO
2.	High cholesterol level?	YES	NO
3.	Diabetes (sugar diabetes)?	YES	NO
4.	Problems with heart and blood circulation?	YES	NO
5.	Depression, anxiety, or emotional problems?	YES	NO
6.	Alcoholism or drug problems?	YES	NO
7.	Arthritis or rheumatism?	YES	NO
8.	Cancer?	YES	NO

Have you been told by a doctor, nurse, or other health professional that you should do any of the following to protect or improve your health?

1.	Watch your diet (for example, lower intake of calories, salt, fats, or sweets)	YES	NO
2.	Reduce your weight	YES	NO
3.	Cut down or stop smoking	YES	NO
4.	Cut down or stop drinking alcohol	YES	NO
5.	Follow an exercise program	YES	NO
6.	Relax more and reduce stress	YES	NO
7.	Take medication	YES	NO

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Section 2

Weight Gain and Loss

This section contains a number of questions about your weight and changes in it. In case you don't remember an exact number, please give your best estimate.

1. How tall are you without shoes?

   _____ _____
   Feet & Inches

2. How much do you currently weigh?

   _____
   Pounds

3. How much did you weigh at age 18 years?

   _____
   Pounds

4. How would you describe your weight for most of the time before age 18 years?
   (Please circle appropriate letter)

Very Underweight	Slightly Underweight	Average	Slightly Overweight	Very Overweight
(A)	(B)	(C)	(D)	(E)

5. What is the most you have weighed at any age?

   _____
   Pounds

6. What has been your usual or average weight as an adult (after 18 years of age)?

   _____
   Pounds

7. What do you think is the best possible weight for you?

   _____
   Pounds

8. As an adult how would you describe your weight for most of the time (since age 18 years)?
   (Please circle appropriate letter)

Very Underweight	Slightly Underweight	Average	Slightly Overweight	Very Overweight
(A)	(B)	(C)	(D)	(E)

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9. As an adult, what has been your largest **gain** in weight during one year?

_____ Pounds

10. As an adult, what has been your largest **loss** in weight during one year, <u>for any reason</u>?

_____ Pounds

11. As an adult, what has been your largest **loss** in weight during one year, <u>when you tried to lose weight</u>?

_____ Pounds

12. As an adult, how much of the time have you been within 20 pounds of your best possible weight? (Please circle appropriate letter)

None <u>of the time</u>	A little <u>of the time</u>	Some <u>of the time</u>	A good bit <u>of the time</u>	Most <u>of the time</u>	All <u>of the time</u>
(A)	(B)	(C)	(D)	(E)	(F)

13. As an adult, how much of the time have you been on a diet to control your weight? (Please circle appropriate letter)

None <u>of the time</u>	A little <u>of the time</u>	Some <u>of the time</u>	A good bit <u>of the time</u>	Most <u>of the time</u>	All <u>of the time</u>
(A)	(B)	(C)	(D)	(E)	(F)

Please answer the following questions by circling "Yes" or "No."

14. Did you ever intentionally keep your weight more than 20 pounds below what is average for your height?	YES	NO
15. Was there ever a time when you were below average in weight but you still had a great fear of gaining weight or becoming fat?	YES	NO
16. Was there ever a time when your family or friends thought you were too thin, but you were still fearful of gaining weight or becoming fat?	YES	NO
17. Have you ever gone on eating binges in which you felt that you could not control how much or what you ate?	YES	NO
18. Have you ever tried to prevent gaining weight after you ate too much by purging (like making yourself vomit or taking laxatives)?	YES	NO
19. Was there ever a time period of 3 months or more when your binge eating and purging both occurred, on average, at least twice a week?	YES	NO

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Section 3

Eating Habits and Diet

This section has two parts which consist of a number of statements about eating. In part A each statement can be answered TRUE or FALSE. Read each statement and decide how you feel about it. If you agree with the statement, or if you feel that it is TRUE about you, answer TRUE by circling the T next to the statement. If you disagree with the statement, or if you feel it is FALSE as applied to you, answer FALSE by circling the F next to the statement.

1. When I smell a sizzling steak or see a juicy piece of meat, I find it very difficult to keep from eating, even if I have just finished a meal	T	F
2. I usually eat too much at social occasions, like parties or picnics	T	F
3. I am usually so hungry that I eat more than three times a day	T	F
4. When I have eaten my quota of calories, I am usually good about not eating any more	T	F
5. Dieting is so hard for me because I just get too hungry	T	F
6. I deliberately take small helpings as a means of controlling my weight	T	F
7. Sometimes things just taste so good that I keep on eating even when I am no longer hungry	T	F
8. Since I am often hungry, I sometimes wish that while I am eating, an expert would tell me that I have had enough or that I can have something more to eat	T	F
9. When I feel anxious, I find myself eating	T	F
10. Life is too short to worry about dieting	T	F
11. Since my weight goes up and down, I have gone on reducing diets more than once	T	F
12. I often feel so hungry that I just have to eat something	T	F
13. When I am with someone who is overeating, I usually overeat too	T	F
14. I have a pretty good idea of the number of calories in common foods	T	F
15. Sometimes when I start eating, I just can't seem to stop	T	F
16. It is not difficult for me to leave something on my plate	T	F
17. At certain times of the day, I get hungry because I have gotten used to eating then	T	F
18. While on a diet, if I eat a food that is not allowed, I consciously eat less for a period of time to make up for it	T	F
19. Being with someone who is eating often makes me hungry enough to eat also	T	F
20. When I feel blue, I often overeat	T	F
21. I enjoy eating too much to spoil it by counting calories or watching my weight	T	F
22. When I see a real delicacy, I often get so hungry that I have to eat right away	T	F
23. I often stop eating when I am not really full as a conscious means of limiting the amount that I eat	T	F
24. I get so hungry that my stomach often seems like a bottomless pit	T	F
25. My weight has hardly changed at all in the last ten years	T	F
26. I am always hungry so it is hard for me to stop eating before I finish the food on my plate	T	F
27. When I feel lonely, I console myself by eating	T	F
28. I consciously hold back at meals in order not to gain weight	T	F
29. I sometimes get very hungry late in the evening or at night	T	F
30. I eat anything I want, any time I want	T	F
31. Without thinking about it, I take a long time to eat	T	F
32. I count calories as a conscious means of controling my weight	T	F
33. I do not eat some foods because they make me fat	T	F
34. I am always hungry enough to eat at any time	T	F
35. I pay a great deal of attention to changes in my figure	T	F
36. While on a diet, if I eat a food that is not allowed, I often splurge and eat other high calorie foods	T	F

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf

Source: https://www.industrydocuments.ucsf.edu/docs/vtxl0001

In part B read each statement and decide how you feel about it. Circle the letter which best answers the question.

37. How often are you dieting in a conscious effort to control your weight?

rarely	sometimes	usually	always
(A)	(B)	(C)	(D)

38. Would a weight fluctuation of 5 lbs. affect the way you live your life?

not at all	slightly	moderately	very much
(A)	(B)	(C)	(D)

39. How often do you feel hungry?

only at meal times	sometimes between meals	often between meals	almost always
(A)	(B)	(C)	(D)

40. Do your feelings of guilt about overeating help you control your food intake?

rarely	sometimes	usually	always
(A)	(B)	(C)	(D)

41. How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?

easy	slightly difficult	moderately difficult	very difficult
(A)	(B)	(C)	(D)

42. How conscious are you of what you are eating?

not at all	slightly	moderately	extremely
(A)	(B)	(C)	(D)

43. How frequently do you avoid "stocking up" on tempting foods?

almost never	seldom	usually	almost always
(A)	(B)	(C)	(D)

44. How likely are you to shop for low calorie foods?

unlikely	slightly likely	moderately likely	very likely
(A)	(B)	(C)	(D)

45. Do you eat sensibly in front of others and splurge alone?

never	rarely	often	always
(A)	(B)	(C)	(D)

46. How likely are you to consciously eat slowly in order to cut down on how much you eat?

unlikely	slightly likely	moderately likely	very likely
(A)	(B)	(C)	(D)

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http://legacy.library.ucsf.edu/tid/olr07a00/pdf

47. How frequently do you skip desert because you are no longer hungry?

almost never	seldom	at least once a week	almost every day
(A)	(B)	(C)	(D)

48. How likely are you to consciously eat less than you want?

unlikely	slightly likely	moderately likely	very likely
(A)	(B)	(C)	(D)

49. Do you go on eating binges even though you are not hungry?

never	rarely	sometimes	at least once a week
(A)	(B)	(C)	(D)

50. On a scale of 0 to 10, where 0 means no restraint in eating (eat whatever you want, whenever you want it) and 10 means total restraint (constantly limiting food intake and never "giving in"), what number would you give yourself?

(0)
eat whatever you want, whenever you want it

(1)
(2)
usually eat whatever you want, whenever you want

(3)
(4)
often eat whatever you want, whenever you want

(5)
(6)
often limit food intake, but often "give in"

(7)
(8)
usually limit food intake, rarely "give in"

(9)
(10)
usually limit food intake, never "give in"

51. To what extent does this statement describe your eating behavior? "I start dieting in the morning, but because of any number of things that happen during the day, by evening I have given up and eat what I want, promising myself to start dieting again tomorrow."

not like me	little like me	pretty good description of me	describes me perfectly
(A)	(B)	(C)	(D)

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In this part there is a list of foods. As you read the list think back over the past year and decide if you have eaten the food . Then decide how often you have eaten it.

There are five answers to choose from:

0	1	2	3	4
Never	Rarely	Most Months	Most Weeks	Most Days

Choose the number which best describes how often you ate each food in th last year.

	0 Never	1 Rarely	2 Most Months	3 Most Weeks	4 Most Days
1. Beef - steaks and roasts	0	1	2	3	4
2. Beef stew, pot pie, with vegetables	0	1	2	3	4
3. Hamburgers, cheeseburgers, meat loaf	0	1	2	3	4
4. Bacon	0	1	2	3	4
5. Pork, including chops, roasts	0	1	2	3	4
6. Ham, lunch meats	0	1	2	3	4
7. Sausage	0	1	2	3	4
8. Hot dogs	0	1	2	3	4
9. Livers	0	1	2	3	4
10. Liverwurst	0	1	2	3	4
11. Fried chicken	0	1	2	3	4
12. Chicken/turkey, roasted, stewed	0	1	2	3	4
13. Tuna fish, salad, casserole	0	1	2	3	4
14. Fried fish or fish sandwich	0	1	2	3	4
15. Shellfish	0	1	2	3	4
16. Other fish, broiled or baked	0	1	2	3	4
17. Chili with beans	0	1	2	3	4
18. Pizza	0	1	2	3	4
19. Eggs	0	1	2	3	4
20. Whole milk, drinks with whole milk	0	1	2	3	4
21. 2% milk, drinks with 2% milk	0	1	2	3	4
22. Skim milk or buttermilk	0	1	2	3	4
23. Ice cream	0	1	2	3	4

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Choose the number which best describes how often you ate each food in the last year.

	0 Never	1 Rarely	2 Most Months	3 Most Weeks	4 Most Days
24. Frozen yogurt	0	1	2	3	4
25. Flavored yogurt	0	1	2	3	4
26. Cottage cheese	0	1	2	3	4
27. Other cheese and cheese spreads	0	1	2	3	4
28 Mixed dishes with cheese	0	1	2	3	4
29. Butter on bread or rolls	0	1	2	3	4
30. Margarine on bread or rolls	0	1	2	3	4
31. White bread, bagels, crackers	0	1	2	3	4
32. Dark bread	0	1	2	3	4
33. Corn breads	0	1	2	3	4
34. Biscuits, muffins, burger rolls	0	1	2	3	4
35. Doughnuts, cookies, cakes and pastries	0	1	2	3	4
36. Cooked cereals	0	1	2	3	4
37. High fiber cereals	0	1	2	3	4
38. Fortified cereal	0	1	2	3	4
39. Other cold cereals	0	1	2	3	4
40. Rice	0	1	2	3	4
41. Pasta with tomato sauce	0	1	2	3	4
42. Peanuts and peanut butter	0	1	2	3	4
43. String, green beans	0	1	2	3	4
44. Other beans	0	1	2	3	4
45. Peas	0	1	2	3	4
46. Corn	0	1	2	3	4
47. Carrots	0	1	2	3	4
48. Tomatoes, tomato juice	0	1	2	3	4
49. French fries, fried potatoes	0	1	2	3	4
50. Sweet potatoes, yams	0	1	2	3	4
51. Broccoli	0	1	2	3	4
52. Cole slaw, cabbage, sauerkraut	0	1	2	3	4
53. Cauliflower or brussel sprouts	0	1	2	3	4
54. Spinach (cooked)	0	1	2	3	4
55. Spinach (raw)	0	1	2	3	4
56. Winter squash, baked squash	0	1	2	3	4
57. Other vegetables	0	1	2	3	4

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf

Source: https://www.industrydocuments.ucsf.edu/docs/ytxl0001

Choose the number which best describes how often you ate each food in the last year.

	0 Never	1 Rarely	2 Most Months	3 Most Weeks	4 Most Days
58. Vegetable soups	0	1	2	3	4
59. Other soups	0	1	2	3	4
60. Apples, applesauce, pears	0	1	2	3	4
61. Bananas	0	1	2	3	4
62 Cantaloupe	0	1	2	3	4
63. Grapefruit	0	1	2	3	4
64. Oranges	0	1	2	3	4
65. Canned, frozen, dried peaches	0	1	2	3	4
66. Fresh peaches, apricots	0	1	2	3	4
67. Fresh strawberries	0	1	2	3	4
68. Watermelon	0	1	2	3	4
69. Other fruit	0	1	2	3	4
70. Orange juice or grapefruit juice	0	1	2	3	4
71. Lemon in tea	0	1	2	3	4
72. Other fruit juices	0	1	2	3	4
73. Pumpkin pie, sweet potato pie	0	1	2	3	4
74. Other pies	0	1	2	3	4
75. Chocolate candy	0	1	2	3	4
76. Other candy, jelly, honey, brown sugar	0	1	2	3	4
77. Salty snacks	0	1	2	3	4
78. Regular coffee	0	1	2	3	4
79. Decaffinated coffee	0	1	2	3	4
80. Tea	0	1	2	3	4
81. Regular soft drinks	0	1	2	3	4
82. Diet soft drinks	0	1	2	3	4
83. Beer	0	1	2	3	4
84. Wine	0	1	2	3	4
85. Sugar in coffee and tea	0	1	2	3	4
86. Sugar added to cereal	0	1	2	3	4
87. Gravies	0	1	2	3	4
88. Mayonnaise	0	1	2	3	4
89. Fat on vegetables, potatoes	0	1	2	3	4
90. Red chili sauce	0	1	2	3	4

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf

Source: https://www.industrydocuments.ucsf.edu/docs/fyjl0003

Section 4

Physical Activity and Exercise

For each of the following questions, please circle the number that best describes your physical activity <u>DURING THE PAST YEAR</u>. (Circle only one number on each line.)

1 None of the Time	2 A Little of the Time	3 Some of the Time	4 A Good Bit of the Time	5 Most of the Time	6 All of the Time

	1 None of the Time	2 A Little of the Time	3 Some of the Time	4 A Good Bit of the Time	5 Most of the Time	6 All of the Time
1. During the past year, how much of the time has your health kept you from working at a job, doing work around the house, or going to school?	1	2	3	4	5	6
2. During the past year, how much of the time did your activities involve little or no physical effort, such as sitting?	1	2	3	4	5	6
3. During the past year, how much of the time did your activities involve mild physical effort, such as walking slowly?.	1	2	3	4	5	6
4. During the past year, how much of the time did your activities include moderate physical effort, such as climbing stairs or walking fast? . .	1	2	3	4	5	6
5. During the past year, how much of the time did your activities involve hard physical effort that made you sweat and your heart beat fast, such as running or heavy lifting?	1	2	3	4	5	6

6. During the past year (52 weeks), about how many weeks did you have at least one occasion in which you exercised hard enough to sweat, breath deeply, and to make your heart beat fast?

_____
Number of weeks

7. During the weeks in which you exercised hard at least once in during the last year, how many times per week, on average, did you exercise enough to sweat and breathe deeply? (Please circle appropriate letter)

Once per week (A)	Twice per week (B)	3 times per week (C)	4 times per week (D)	5 or more times per week (E)

8. How long, on average, did you exercise actively on each occasion of hard physical exercise during the last year? (Please circle appropriate letter)

less than 20 min. (A)	20-30 min. (B)	31-40 min. (C)	41-50min. (D)	more than 50 min. (E)

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/dxl0001

What is the longest time you have maintained a regular exercise program?

_____ 1. Have never gone on an exercise program
_____ 2. Less than one week
_____ 3. At least one week but less than one month
_____ 4. At least one month but less than six months
_____ 5. At least six months but less than one year
_____ 6. One year or more

If you have ever started a regular exercise program at home or elsewhere, please answer the following questions by circling "Yes" or "No." If you never started an exercise program, please go on to the next section.

1.	I would hate to quit exercising because it makes me feel so good.	YES	NO
2.	Exercise is so important to me that I do it even when I have an injury that might be made worse.	YES	NO
3.	When I feel anxious, physical exercise helps me relax.	YES	NO
4.	I have started on exercise programs more than once, but in the past I have always stopped within one year.	YES	NO
5.	Once I get off my exercise schedule, I have difficulty starting back again.	YES	NO
6.	When I feel blue, I often skip anything involving physical exercise.	YES	NO
7.	If the weather is not good, I am usually successful in making myself exercise as planned.	YES	NO
8.	If I have drunk alcohol shortly before a time intended for exercise, I usually exercise anyway.	YES	NO
9.	If friends I am with don't want to exercise, I often skip my own exercise	YES	NO
10.	It is difficult for me to exercise regularly because other things occur that I want to do or must do.	YES	NO
11.	At times when I suddenly stopped exercising, I felt so bad that I had trouble working or enjoying my usual activities	YES	NO

If you answered YES to Question 11, please check each of the following problems which occurred when you stopped exercising.

_____ 1. feeling sad or depressed
_____ 2. trouble sleeping
_____ 3. being easily irritated or angry
_____ 4. feeling anxious
_____ 5. Having difficulty concentrating
_____ 6. feeling restless or fidgety
_____ 7. having an increased heart rate
_____ 8. eating more or gaining weight
_____ 9. other problems

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/vdxl0001

Section 5

In this section you will find statements people might use to describe their attitudes, opinions, interests, and other personal feelings. Try to describe yourself the way you usually or <u>GENERALLY</u> act and feel, not just how you are feeling right now.

Read each statement carefully and decide <u>which choice better describes you</u>, but don't spend too much time deciding on the answer.

Please answer every statement, even if you are not completely sure of the answer.

Remember there are no right or wrong answers — just describe you own personal opinions and feelings.

Each statement can be answered TRUE or FALSE.

To answer, you only need to circle either "T" or "F" after each question. Here is an <u>example</u>:

I understand how to fill out this questionnaire.	(T) F

If you understand how to fill out this questionnaire, circle the "T" to show that the statement is TRUE.

1.	I often try new things just for fun or thrills, even if most people think it is a waste of time	T	F
2.	I usually am confident that everything will go well, even in situations that worry most people	T	F
3.	The most important influences in my life are my ideals of right and wrong	T	F
4.	I am often moved deeply by a fine speech or poetry	T	F
5.	I often feel that I am the victim of circumstances	T	F
6.	Sometimes I feel like everything around me is tilting	T	F
7.	I can usually accept other people as they are, even when they are very different from me	T	F
8.	I believe that miracles happen	T	F
9.	I am quick to volunteer when there is something to be done	T	F
10.	I enjoy getting revenge on people who hurt me	T	F
11.	Often when I am concentrating on something, I lose awareness of the passage of time	T	F
12.	No job is too hard for me to do my best	T	F
13.	Often I feel that my life has little purpose or meaning	T	F
14.	I like to help find a solution to problems so that everyone comes out ahead	T	F
15.	I am a very ambitious person	T	F
16.	I could probably accomplish more than I do,but I don't see the point in pushing myself harder than is necessary to get by	T	F
17.	I often feel tense and worried in unfamiliar situations, even when others feel there is little to worry about	T	F
18.	Please circle true; this is a validity item	T	F
19.	I often do things based on how I feel at the moment without thinking about how they were done in the past	T	F
20.	I usually do things my own way – rather than giving in to the wishes of other people	T	F
21.	I am usually peaceful thanks to the help of the supernatural force that gives love and order to all things	T	F
22.	I often feel so connected to the people around me that it is like there is no separation between us	T	F
23.	I generally don't like people who have different ideas from me	T	F
24.	My personal and social activities are more important than prayer or religious activities	T	F
25.	In most situations my natural responses are based on good habits that I have developed	T	F
26.	I would do almost anything legal in order to become rich and famous, even if I would lose the trust of many old friends	T	F

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/bfxl0001

27. I doubt that anyone has ever received any supernatural help.	T	F
28. I am much more reserved and controlled than most people.	T	F
29. I often have to stop what I am doing because I start worrying about what might go wrong	T	F
30. I like to discuss my experiences and feelings openly with friends instead of keeping them to myself	T	F
31. I am usually eager to get going on any job I have to do	T	F
32. I have less energy and get tired more quickly than most people	T	F
33. I am often called "absent-minded" because I get so wrapped up in what I am doing that I lose track of everything else	T	F
34. The harder a job is the more I like it.	T	F
35. I seldom feel free to choose what I want to do	T	F
36. I often consider another person's feelings as much as my own.	T	F
37. I am often described as an underachiever .	T	F
38. Most of the time I would prefer to do something a little risky (like riding in an automobile over steep hills and sharp turns) rather than having to stay quiet and inactive for a few hours	T	F
39. I often avoid meeting strangers because I lack confidence with people I do not know. .	T	F
40. Sometimes part of my body has seemed smaller than it usually is	T	F
41. I like to please other people as much as I can	T	F
42. I like old "tried and true" ways of doing things much better than trying "new and improved" ways.	T	F
43. Usually I am not able to do things according to their priority of importance to me because of lack of time	T	F
44. I often do things to help protect animals and plants from extinction	T	F
45. I wish I could perform miracles.	T	F
46. I often wish that I was smarter than everyone else.	T	F
47. It gives me pleasure to see my enemies suffer.	T	F
48. I would suffer for the sake of what is right in order to be true to my ideals	T	F

49. I like to be very organized and set up rules for people whenever I can.	T	F
50. It is difficult for me to keep the same interests for a long time because my attention often shifts to something else. . . .	T	F
51. I am not satisfied unless I am working on something.	T	F
52. Repeated practice has given me good habits that are stronger than most momentary impulses or persuasion	T	F
53. I am usually so determined that I continue to work long after other people have given up	T	F
54. I like a challenge better than easy jobs . . .	T	F
55. I am fascinated by the many things in life that cannot be scientifically explained	T	F
56. I have many bad habits that I wish I could break.	T	F
57. I often wait for someone else to provide a solution to my problems.	T	F
58. I often accomplish more than people expect of me	T	F
59. I often spend money until I run out of cash or get into debt from using too much credit.	T	F
60. I think I will have very good luck in the future	T	F
61. I open up quickly to other people, even if I don't know them well	T	F
62. I recover more slowly than most people from minor illnesses or stress	T	F
63. It wouldn't bother me to be alone all the time.	T	F
64. I often feel betrayed by others.	T	F
65. Often I have unexpected flashes of insight or understanding while relaxing	T	F
66. I don't care very much whether other people like me or the way I do things	T	F
67. I receive much comfort and support from my religious beliefs.	T	F
68. I usually try to get just what I want for myself because it is not possible to satisfy everyone anyway.	T	F
69. I have no patience with people who don't accept my views.	T	F
70. I don't seem to understand most people very well.	T	F
71. You don't have to be dishonest to succeed in business.	T	F

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/tpd0002

72. The saying "the early bird catches the worm" describes my attitude.	T	F
73. I sometimes feel so connected to nature that everything seems to be part of one living organism.	T	F
74. In conversations I am much better as a listener than as a talker	T	F
75. I have felt that I might cause something to happen just by thinking too much about it.	T	F
76. I lose my temper more quickly than most people	T	F
77. When I have to meet a group of strangers, I am more shy than most people.	T	F
78. I love to excel at everything I do	T	F
79. I am more sentimental than most people . .	T	F
80. I seem to have a "sixth sense" that sometimes allows me to know what is going to happen	T	F
81. I would not be happy in a job where I did not communicate with other people.	T	F
82. When someone hurts me in any way, I usually try to get even.	T	F
83. My attitudes are determined largely by influences outside my control	T	F
84. Each day I try to take another step toward my goals.	T	F
85. I often wish I was stronger than everyone else.	T	F
86. I like to think about things for a long time before I make a decision.	T	F
87. My popularity is more important to me than devotion to the absolute ideals of universal truth and harmony.	T	F
88. I am more hard-working than most people .	T	F
89. I often need naps or extra rest periods because I get tired so easily	T	F
90. At times I perform certain little rituals to ward off negative influences.	T	F
91. I like to be of service to others	T	F
92. Regardless of any temporary problem that I have to overcome, I always think it will turn out well	T	F
93. No matter how hard a job is, I like to get started quickly	T	F
94. It is hard for me to enjoy spending money on myself, even when I have saved plenty of money	T	F
95. I usually stay calm and secure in situations that most people would find physically dangerous	T	F
96. I often do my best work under difficult circumstances	T	F
97. I like to keep my problems to myself	T	F
98. I have a vivid imagination	T	F
99. I am grateful for supernatural guidance. . .	T	F
100. I like to stay at home better than to travel or explore new places	T	F
101. I do not think it is smart to help weak people who cannot help themselves	T	F
102. Warm friendships with other people are very important to me.	T	F
103. I cannot have any peace of mind if I treat other people unfairly, even if they are unfair to me	T	F
104. People will usually tell me how they feel. . .	T	F
105. I often wish I could stay young forever. . . .	T	F
106. I like to read everything when I am asked to sign papers.	T	F
107. When nothing new is happening, I usually start looking for something that is thrilling or exciting.	T	F
108. Sometimes I have felt like I was part of something with no limits or boundaries in time and space.	T	F
109. I sometimes feel a spiritual connection to other people that I cannot explain in words.	T	F
110. I try to be considerate of other people's feelings, even when they have been unfair to me in the past.	T	F
111. I like to do practical things more than praying or thinking about the mysteries of the universe.	T	F
112. I like it when people can do whatever they want without strict rules and regulations. .	T	F
113. I would probably stay relaxed and outgoing when meeting a group of strangers, even if I were told they are unfriendly.	T	F
114. If there is any supernatural force in the universe, I don't think it affects me personally one way or the other.	T	F
115. Usually I am more worried than most people that something might go wrong in the future	T	F
116. I usually think about all the facts in detail before I make a decision.	T	F

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf

117. I feel it is more important to be sympathetic and understanding of other people than to be practical and tough-minded	T	F
118. I often feel a strong sense of unity with all the things around me	T	F
119. I often quit working if people aren't nice to me	T	F
120. I often wish I had special powers like Superman	T	F
121. Other people control me too much	T	F
122. I am often described as an overachiever	T	F
123. I like to share what I have learned with other people	T	F
124. Religious experiences have helped me understand the real purpose of my life	T	F
125. I often learn a lot from people	T	F
126. Repeated practice has allowed me to become good at many things that help me to be successful	T	F
127. I have sometimes felt that strangers were reading my mind	T	F
128. I am usually able to get other people to believe me, even when I know that what I am saying is exaggerated or untrue	T	F
129. I need much extra rest, support, or reassurance to recover from minor illnesses or stress	T	F
130. I feel an ever-increasing awe of the beauty in all things	T	F
131. I know there are principles for living that no one can violate without suffering in the long run	T	F
132. I don't want to be richer than everyone else	T	F
133. I like to go slow in starting work, even if it is easy to do	T	F
134. I would gladly risk my own life to make the world a better place	T	F
135. Even after thinking about something a long time, I have learned to trust my feelings more than my logical reasons	T	F
136. Sometimes I have felt my life was being directed by a spiritual force greater than any human being	T	F
137. I am only effective doing work that I like	T	F
138. I usually enjoy being mean to anyone who has been mean to me	T	F
139. I have a reputation as someone who is very practical and does not act on emotion	T	F

140. Faith provides my greatest sense of fulfillment and contentment	T	F
141. It is easy for me to organize my thoughts while talking to someone	T	F
142. It has seemed at times as if my body was melting into my surroundings	T	F
143. I usually feel much more confident and energetic than most people, even after minor illnesses or stress	T	F
144. I am strongly moved by sentimental appeals (like when asked to help crippled children)	T	F
145. I usually push myself harder than most people do because I want to do as well as I possibly can	T	F
146. It takes me a long time to warm up to other people	T	F
147. I have so many faults that I don't like myself very much	T	F
148. I have too little time to look for long-term solutions for my problems	T	F
149. I often wish for things that I don't have	T	F
150. I often cannot deal with problems because I just don't know what to do	T	F
151. I often wish I could stop the passage of time	T	F
152. I try with all my heart to understand and obey the moral ideals of universal love and harmony	T	F
153. I hate to make decisions based only on my first impressions	T	F
154. I prefer spending money rather than saving it	T	F
155. I cannot get any comfort from religious preaching because no one really knows what happens after we are dead	T	F
156. I can usually do a good job of stretching the truth to tell a funnier story or to play a joke on someone	T	F
157. Parts of my body occasionally seem dead or unreal	T	F
158. I feel it is foolish and impractical to strive for truth and harmony in all things	T	F
159. If I am embarrassed or humiliated, I get over it very quickly	T	F
160. It is extremely difficult for me to adjust to changes in my usual way of doing things because I get so tense, tired, or worried	T	F

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161. When my work goes unnoticed, I become even more determined to succeed . . . . . T F

162. I usually demand very good practical reasons before I am willing to change my old ways of doing things . . . . . T F

163. I need a lot of help from other people to train me to have good habits. . . . . T F

164. I think that extra-sensory perception (ESP, like telepathy or precognition) is really possible. . . . . T F

165. The boundaries of my body always seem clear. . . . . T F

166. I would like to have warm and close friends with me most of the time . . . . . T F

167. I have so much to do most days that I don't usually have time for contemplation or prayer. . . . . T F

168. I nearly always stay relaxed and carefree, even when nearly everyone else is fearful . T F

169. I find sad songs and movies pretty boring. T F

170. I doubt that any supernatural power has ever helped me personally. . . . . T F

171. Circumstances often force me to do things against my will . . . . . T F

172. It is hard for me to tolerate people who are different from me . . . . . T F

173. I am often described as a dreamer because I place moral ideals before practical considerations. . . . . T F

174. I think that most things that are called miracles are just chance. . . . . T F

175. I would rather be kind than to get revenge when someone hurts me. . . . . T F

176. I have sometimes had the feeling that one of my arms or legs is disconnected from the rest of my body. . . . . T F

177. I often become so fascinated with what I'm doing that I get lost in the moment - like I'm detached from time and place. . . . . T F

178. I do not think I have a real sense of purpose for my life . . . . . T F

179. I really enjoy keeping busy . . . . . T F

180. I try to cooperate with others as much as possible . . . . . T F

181. When I am in deep contemplation or prayer, I sometimes feel warmth and tingling like a powerful current is flowing through my body. . . . . T F

182. I cannot work with people who criticize me often. . . . . T F

183. I often feel tense and worried in unfamiliar situations, even when others feel there is no danger at all . . . . . T F

184. I often follow my instincts, hunches, or intuition without thinking through all the details . . . . . T F

185. I am often successful because of my ambition and hard work. . . . . T F

186. Other people often think that I am too independent because I won't do what they want . . . . . T F

187. I often feel a strong spiritual or emotional connection with all the people around me . T F

188. If reincarnation were true, it would explain some unusual experiences I have had. . . T F

189. It is usually easy for me to like people who have different values from me. . . . . T F

190. Moral ideals are never an acceptable excuse for disobeying the laws of society. . T F

191. I am good at communicating my feelings to others. . . . . T F

192. Good habits have become "second nature" to me – they are automatic and spontaneous actions nearly all the time . . T F

193. I don't mind the fact that other people often know more than I do about something . . . T F

194. I usually try to imagine myself "in other people's shoes", so I can really understand them. . . . . T F

195. I think it is foolish to depend on super-natural guidance to understand the mysteries of life . . . . . T F

196. Principles like fairness and honesty have little role in some aspects of my life . . . . . T F

197. I am better at saving money than most people . . . . . T F

198. I have felt that there were messages for me in the way things were arranged, like in a store window. . . . . T F

199. The moral ideals within me fill my heart with awe and admiration. . . . . T F

200. Even when most people feel it is not important, I often insist on things being done in a strict and orderly way . . . . . T F

201. I am eager to start work on any assigned duty. . . . . T F

202. I feel very confident and sure of myself in almost all social situations. . . . . T F

203. My friends find it hard to know my feelings because I seldom tell them about my private thoughts . . . . . T F

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Source: https://www.industrydocuments.ucsf.edu/docs/txxl0003

204. I have wondered whether the spirits of the dead can influence the living.	T	F
205. I hate to change the way I do things, even if many people tell me there is a new and better way to do it.	T	F
206. I think it is unwise to believe in things that cannot be explained scientifically	T	F
207. I am willing to make many sacrifices to be a success.	T	F
208. I like to imagine my enemies suffering . . .	T	F
209. I am more energetic and tire less quickly than most people	T	F
210. I like to pay close attention to details in everything I do.	T	F
211. I often stop what I am doing because I get worried, even when my friends tell me everything will go well	T	F
212. I am more stubborn than most people. . . .	T	F
213. I often wish I was more powerful than everyone else	T	F
214. I usually am free to choose what I will do .	T	F
215. I make a warm personal connection with most people	T	F
216. Often I become so involved in what I am doing that I forget where I am for a while. .	T	F
217. Members of a team rarely get their fair share.	T	F
218. My confidence in the goodness and order throughout the universe gives me wonderful feelings of comfort and peace. .	T	F
219. Most of the time I would prefer to do something risky (like hang-gliding or parachute jumping) – rather than having to stay quiet and inactive for a few hours. .	T	F
220. Because I so often spend too much money on impulse, it is hard for me to save money – even for special plans like a vacation.	T	F
221. I don't go out of my way to please other people.	T	F
222. Sometimes I have to compromise my moral ideals in order to get a job done to my advantage.	T	F
223. I am not shy with strangers at all.	T	F
224. I often give in to the wishes of friends	T	F
225. I often drag my heels a while before starting any project	T	F

226. I spend most of my time doing things that seem necessary but not really important to me.	T	F
227. I don't think that religious or ethical principles about what is right and wrong should have much influence in business decisions	T	F
228. I am sure that whatever support and comfort I might need will always be provided to me.	T	F
229. I often try to put aside my own judgments so that I can better understand what other people are experiencing	T	F
230. Many of my habits make it hard for me to accomplish worthwhile goals	T	F
231. I like to strive for bigger and better things. .	T	F
232. I have made real personal sacrifices in order to make the world a better place – like trying to prevent war, poverty and injustice	T	F
233. I never worry about terrible things that might happen in the future.	T	F
234. I have had the momentary feeling that my body has become mis-shapen.	T	F
235. I almost never get so excited that I lose control of myself.	T	F
236. I often give up a job if it takes much longer than I thought it would	T	F
237. I like other people to know that I really care about them	T	F
238. I prefer to start conversations, rather than waiting for others to talk to me	T	F
239. Most of the time I quickly forgive anyone who does me wrong	T	F
240. When I am truly at peace, my body feels warmth and tingling – like I am being engulfed in a burning flame of love.	T	F
241. My actions are determined largely by influences outside my control.	T	F
242. I have sometimes sensed an evil presence around me, although I could not see it	T	F
243. I prefer to wait for someone else to take the lead in getting things done.	T	F
244. I usually respect the opinions of others . . .	T	F
245. I often ask for supernatural forgiveness for violating the absolute ideals of truth and harmony in all things.	T	F
246. I have had experiences that made my role in life so clear to me that I felt very excited and happy.	T	F

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247. It is fun for me to buy things for myself . . .	T	F
248. I believe that I have experienced extra-sensory perception myself.	T	F
249. I have often been called an "eager beaver" because of my enthusiasm for hard work. .	T	F
250. When I am in deep contemplation or prayer, I sometimes feel that I am directly connected to a supernatural source of love and peace.	T	F
251. My behavior is strongly guided by certain goals that I have set for my life	T	F
252. It is usually foolish to promote the success of other people	T	F
253. I often wish I could live forever.	T	F
254. When someone points out my mistakes, I work extra hard to correct them.	T	F
255. I usually like to stay cool and detached from other people.	T	F
256. I am more likely to cry at a sad movie than most people.	T	F
257. I will not let anything get in the way of my success.	T	F
258. I recover more quickly than most people from minor illnesses or stress	T	F
259. I often break rules and regulations when I think I can get away with it	T	F
260. I won't give up what I am doing just because of a long run of unexpected failures	T	F
261. I need much more practice in developing good habits before I will be able to trust myself in many tempting situations.	T	F
262. I wish other people didn't talk as much as they do.	T	F
263. I would rather read a book than talk about my feelings with another person . . .	T	F
264. Everyone should be treated with dignity and respect, even if they seem to be unimportant or bad.	T	F
265. I like to make quick decisions so I can get on with what has to be done.	T	F
266. I wish I had more control over everything .	T	F
267. I usually have good luck in whatever I try to do	T	F
268. I am usually confident that I can easily do things that most people would consider dangerous (such as driving an automobile fast on a wet or icy road).	T	F

269. I feel that there is a supernatural source of love and peace that often helps me in the way that is really needed	T	F
270. Sometimes when I look at things like tables and chairs, they seem strange. . . .	T	F
271. I like to explore new ways to do things . . .	T	F
272. Please circle true; this is a validity item. . .	T	F
273. I enjoy saving money more than spending it on entertainment or thrills	T	F
274. Individual rights are more important than the needs of any group.	T	F
275. I have had personal experiences in which I felt in contact with a divine and wonderful spiritual power	T	F
276. Dishonesty only causes problems if you get caught	T	F
277. I have had moments of great joy in which I suddenly had a clear, deep feeling of oneness with all that exists	T	F
278. Good habits make it easier for me to do things the way I want.	T	F
279. Most people seem more resourceful than I am	T	F
280. Other people and conditions are often to blame for my problems	T	F
281. When I fail at something at first, I become even more determined to do a better job . .	T	F
282. It gives me pleasure to help others, even if they have treated me badly.	T	F
283. I often feel like I am a part of the spiritual force on which all life depends.	T	F
284. I am more strongly guided by practical considerations than by my moral ideals. . .	T	F
285. Even when I am with friends, I prefer not to "open up" very much.	T	F
286. I usually can stay "on the go" all day without having to push myself.	T	F
287. If something doesn't work as I expected, I am more likely to quit than to keep going for a long time.	T	F
288. I nearly always think about all the facts in detail before I make a decision, even when other people demand a quick decision.	T	F
289. I am not very good at talking my way out of trouble when I am caught doing something wrong.	T	F
290. I would rather be alone than deal with other people's problems.	T	F

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291. I am more of a perfectionist than most people	T	F
292. Whether something is right or wrong is just a matter of opinion	T	F
293. I think my natural responses now are usually consistent with my principles and long-term goals	T	F
294. I believe that all life depends on some spiritual order or power that cannot be completely explained	T	F
295. I think I would stay confident and relaxed when meeting strangers, even if I were told they are angry at me	T	F
296. People find it easy to come to me for help, sympathy, and warm understanding	T	F
297. I am slower than most people to get excited about new ideas and activities	T	F
298. I want many things that I don't have	T	F
299. I have trouble telling a lie, even when it is meant to spare someone else's feelings	T	F
300. I like to be quick to respond to any request for work	T	F
301. I don't want to be more admired than everyone else	T	F
302. Often when I look at an ordinary thing, something wonderful happens – I get the feeling that I am seeing it fresh for the first time	T	F
303. Most people I know look out only for themselves, no matter who else gets hurt	T	F
304. I usually feel tense and worried when I have to do something new and unfamiliar	T	F
305. I often push myself to the point of exhaustion or try to do more than I really can	T	F
306. Some people think I am too stingy or tight with my money	T	F
307. When I fail to master something at first, it becomes my personal challenge to succeed	T	F
308. Reports of mystical experiences are probably just wishful thinking	T	F
309. My will power is too weak to overcome very strong temptations, even if I know I will suffer as a consequence	T	F
310. I want to be the best at everything I do	T	F
311. I hate to see anyone suffer	T	F
312. I know what I want to do in my life	T	F
313. I regularly take time to consider whether what I am doing is right or wrong	T	F
314. Things often go wrong for me unless I am very careful	T	F
315. It is easy for other people to get close to me emotionally	T	F
316. If I am feeling upset, I usually feel better around friends than when left alone	T	F
317. I don't think it is possible for one person to share feelings with someone else who hasn't had the same experiences	T	F
318. It often seems to other people like I am in another world because I am so completely unaware of things going on around me	T	F
319. I wish I were better looking than everyone else	T	F
320. I have lied a lot on this questionnaire	T	F
321. I usually stay away from social situations where I would have to meet strangers, even if I am assured that they will be friendly	T	F
322. I love the blooming of flowers in the spring as much as seeing an old friend again	T	F
323. I like to do a job quickly and then volunteer for more	T	F
324. I usually look at a difficult situation as a challenge or opportunity	T	F
325. People involved with me have to learn how to do things my way	T	F
326. I cannot accept things that are not done exactly right	T	F

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Section 6

Cigarette Smoking

Please answer the following questions by circling "Yes" or "No."

1.	Have you ever smoked cigarettes?	YES NO
2.	Have you smoked at least 100 cigarettes in your entire life (5 packs = 100 cigarettes)? .	YES NO
3.	Have you ever smoked 1 or more cigarettes daily for a year or more?	YES NO
4.	Have you smoked any cigarettes during the past six months?	YES NO

If you answered 'NO' to question 3, please skip the rest of this section and go to the next section. If you ever smoked cigarettes daily for at least a year, please answer the questions below.

5. When smoking the heaviest, how many cigarettes per day did you smoke on average? (check only one answer)

_____ 1. 10 or less (less than 1/2 pack)
_____ 2. 11 to 20 (1/2 to 1 pack)
_____ 3. 21 to 30 (1 to 1 1/2 packs)
_____ 4. 31 to 40 (1 1/2 to 2 packs)
_____ 5. 41 or more (more than 2 packs)

6. When smoking daily, how soon after waking up did/do you smoke your first cigarette? (check only one answer)

_____ 1. immediately (within 5 minutes)
_____ 2. within 6 to 30 minutes
_____ 3. between 30 minutes and 1 hour
_____ 4. after 1 hour

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Please answer the following questions by circling "Yes" or "No."

8.	When smoking daily, do/did you find it difficult to keep from smoking in places where it is forbidden (for example, non-smoking areas like at the movies or at work)?	YES NO
9.	When smoking daily, do/did you smoke more frequently during the first hours after waking than during the rest of the day?	YES NO
10.	When smoking daily, do/did you ever smoke when you were so ill that you had to stay in bed most of the day?	YES NO
11.	As a daily smoker, did you have to keep increasing the number of cigarettes you smoked in order to enjoy their effects?	YES NO

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Source: https://www.industrydocuments.ucsf.edu/docs/yxfc0001

12. At times when you suddenly stopped daily smoking, did you feel so bad that you had trouble working or enjoying your usual activities? (circle YES or NO)

YES NO

If you answered YES to Question 12, please check each of the following problems which occured when you stopped smoking.

_____ 1. feeling sad or depressed
_____ 2. trouble sleeping
_____ 3. being easily irritated or angry
_____ 4. feeling anxious
_____ 5. Having difficulty concentrating
_____ 6. feeling restless or fidgety
_____ 7. having a slower heart rate
_____ 8. eating more or gaining weight
_____ 9. other problems

Please answer the following questions by circling "Yes" or "No."

13. As a daily smoker, have you found yourself smoking more than you intended?	YES	NO
14. Do you feel you were ever addicted to smoking cigarettes?	YES	NO
15. Have you always been able to stop smoking when you want to?	YES	NO
16. Have you ever gone to anyone for help to stop smoking?.....	YES	NO
17. Have you ever used nicotine gum or skin patches to stop smoking?	YES	NO
18. Have you ever been a regular chain-smoker? (By chain-smoking we mean continuous cigarette smoking during a great part of the day, like people who usually light up one cigarette with the one they are now smoking).....	YES	NO
19. When smoking daily, do/did you lose time from work because of smoking?	YES	NO
20. When smoking daily, do/did you give up social or recreational activities where smoking is forbidden?	YES	NO
21. When smoking daily, does/did your desire for a cigarette ever disrupt the activities you were involved in?	YES	NO
22. Do/did you use tobacco despite a serious physical disorder that you think could be made worse by tobacco use?	YES	NO
23. Has a doctor ever told you that you had a health problem caused by smoking too much? ..	YES	NO

24. Since you started smoking daily, what is the longest time you have gone without smoking anything? (check only one answer)

_____ 1. Never gone without smoking
_____ 2. Less than a day
_____ 3. More than a day but less than a week
_____ 4. More than a week but less than a month
_____ 5. More than a month but less than a year
_____ 6. More than a year

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Source: https://www.industrydocuments.ucsf.edu/docs/vtxl0001

Section 7

Alcohol Consumption

1. Have you ever drunk alcoholic beverages, such as beer, wine, wine coolers, or liquor? (circle YES or NO)

YES NO

2. A drink of alcohol is one can or bottle of beer, 1 glass of wine, 1 can or bottle of wine cooler, or 1 shot of liquor. Have you had at least 100 drinks in your entire life? (circle YES or NO)

YES NO

3. What is the highest frequency that you drank alcohol during any period of 12 months (one year)? (check your highest frequency only)

_____ 1. Does not apply - never drank
_____ 2. Less than one drinking occasion per month
_____ 3. One drinking occasion per month
_____ 4. At least one drinking occasion per week
_____ 5. Drinking on most days of the week
_____ 6. Drinking almost every day

4. During your heaviest year of drinking, how many drinks would you consume, on average, during a drinking occasion? (check only one answer)

_____ 1. Does not apply - never drank
_____ 2. One drink per occasion
_____ 3. Two drinks per occasion
_____ 4. Three drinks per occasion
_____ 5. Four drinks per occasion
_____ 6. Five or more drinks per occasion

5. During the past year, was there any occasion that you had 5 or more drinks? (circle YES or NO)

YES NO

6. During the last six months, have you had at least one drink of any alcoholic beverage? (circle YES or NO)

YES NO

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Source: https://www.industrydocuments.ucsf.edu/docs/dxxl0001

Below is a list of questions about your use of alchohol.
Please answer by circling "Yes" or "No."

1.	Do you feel you are a normal drinker? (By normal we mean you drink less than or as much as most other people.)	YES	NO
2.	Does your wife, husband, a parent, or other near relative ever worry or complain about your drinking?	YES	NO
3.	Do you ever feel guilty about your drinking?	YES	NO
4.	Do friends or relatives think you are a normal drinker?	YES	NO
5.	Are you able to stop drinking when you want to?	YES	NO
6.	Have you ever attended a meeting of Alcoholics Anonymous?	YES	NO
7.	Has drinking ever created problems between you and your wife, husband, a parent, or other near relative	YES	NO
8.	Have you ever gotten into trouble at work because of drinking?	YES	NO
9.	Have you ever neglected your obligations, your family, or your work for two or more days in a row because you were drinking?	YES	NO
10.	Have you ever gone to anyone for help about your drinking?	YES	NO
11.	Have you ever been in a hospital because of drinking?	YES	NO
12.	Have you ever been arrested for drunken driving, driving while intoxicated, or driving under the influence of alcoholic beverages?	YES	NO
13.	Have you ever been arrested, even for a few hours, because of other drunken behavior?	YES	NO

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Section 8

Below is a list of the ways you might have felt or behaved. Please circle how often you have felt this way <u>DURING THE PAST WEEK</u>.

0	1	2	3
Rarely or None of the Time (less than 1 day)	Some or a Little of the Time (1-2 days)	Occasionally or a Moderate Amount of Time (3-4 days)	Most or All of the Time (5-7 days)

1.	I was bothered by things that usually don't bother me.	0	1	2	3
2.	I did not feel like eating; my appetite was poor	0	1	2	3
3.	I felt that I could not shake off the blues even with help from my family or friends	0	1	2	3
4.	I felt that I was just as good as other people	0	1	2	3
5.	I had trouble keeping my mind on what I was doing	0	1	2	3
6.	I felt depressed.	0	1	2	3
7.	I felt that everything I did was an effort	0	1	2	3
8.	I felt hopeful about the future.	0	1	2	3
9.	I thought my life had been a failure	0	1	2	3
10.	I felt fearful	0	1	2	3
11.	My sleep was restless	0	1	2	3
12.	I was happy.	0	1	2	3
13.	I talked less than usual	0	1	2	3
14.	I felt lonely.	0	1	2	3
15.	People were unfriendly	0	1	2	3
16.	I enjoyed life	0	1	2	3
17.	I had crying spells	0	1	2	3
18.	I felt sad.	0	1	2	3
19.	I felt that people dislike me	0	1	2	3
20.	I could not get "going"	0	1	2	3

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Source: https://www.industrydocuments.ucsf.edu/docs/vtxl0001

Section 9

Lifestyle Choices and Plans

1. Do you think you could improve or protect your health by changes in any of the following lifestyle areas? (check as many as apply)

_____ 1. Better weight control
_____ 2. Healthier foods in diet
_____ 3. More exercise
_____ 4. Less tobacco smoking
_____ 5. Less alcohol drinking
_____ 6. Reduction of stress
_____ 7. Getting long-term goals and values in better balance with interests and emotional needs

2. Have you tried to make changes in any of these areas in the past? (check as many as apply)

_____ 1. Better weight control
_____ 2. Healthier foods in diet
_____ 3. More exercise
_____ 4. Less tobacco smoking
_____ 5. Less alcohol drinking
_____ 6. Reduction of stress
_____ 7. Getting long-term goals and values in better balance with interests and emotional needs

3. Have you been successful in fulfilling your intentions in any of these areas in the past? (check as many as apply)

_____ 1. Better weight control
_____ 2. Healthier foods in diet
_____ 3. More exercise
_____ 4. Less tobacco smoking
_____ 5. Less alcohol drinking
_____ 6. Reduction of stress
_____ 7. Getting long-term goals and values in better balance with interests and emotional needs

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4. Would you like to make improvements in any of the following lifestyle areas? (check as many as apply)

_____ 1. Better weight control
_____ 2. Healthier foods in diet
_____ 3. More exercise
_____ 4. Less tobacco smoking
_____ 5. Less alcohol drinking
_____ 6. Reduction of stress
_____ 7. Getting long-term goals and values in better balance with interests and emotional needs

5. Sometimes we all imagine goals that would be desirable, but that are not practical or valuable enough for all the trouble they would be. For example, most people quickly find that resolutions they make at the beginning of each new year are not practical. Considering your overall satisfaction with your current health and lifestyle, do you think it is practical for you to try to make changes in any of the following areas in the near future? (check as many as apply)

_____ 1. Better weight control
_____ 2. Healthier foods in diet
_____ 3. More exercise
_____ 4. Less tobacco smoking
_____ 5. Less alcohol drinking
_____ 6. Reduction of stress
_____ 7. Getting long-term goals and values in better balance with interests and emotional needs

6. Even if you could make some improvements, you may prefer to continue as you have been doing. In which of the following aspects of your life have you made a definite decision to try to make improvements as soon as possible? (check as many as apply)

_____ 1. Better weight control
_____ 2. Healthier foods in diet
_____ 3. More exercise
_____ 4. Less tobacco smoking
_____ 5. Less alcohol drinking
_____ 6. Reduction of stress
_____ 7. Getting long-term goals and values in better balance with interests and emotional needs

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7. Are you firmly convinced and certain that you are determined enough to succeed in improving in all the areas you listed earlier? Please check below only those that you are <u>strongly determined and confident that you are ready to do whatever it takes</u> to change now. (check as many as apply)

_____ 1. Better weight control

_____ 2. Healthier foods in diet

_____ 3. More exercise

_____ 4. Less tobacco smoking

_____ 5. Less alcohol drinking

_____ 6. Reduction of stress

_____ 7. Getting long-term goals and values in better balance with interests and emotional needs

8. Have you already developed a detailed plan or program for change in which you have worked out the necessary steps or stages that will have to be accomplished between your starting point and your desired long term goals. You may have begun this program of change or be ready to start now. Please check below only those areas in which you have <u>a detailed plan and improvement program</u> that you have started or that you are ready to start. (check as many as apply)

_____ 1. Better weight control

_____ 2. Healthier foods in diet

_____ 3. More exercise

_____ 4. Less tobacco smoking

_____ 5. Less alcohol drinking

_____ 6. Reduction of stress

_____ 7. Getting long-term goals and values in better balance with interests and emotional needs

THANK YOU!
You have finished the questionnaire!

Please fill out the required payment form on the next page.

May we contact you again in the future to see how you are doing? If you say yes now, you may still decide not to participate in the future. If you say no now, we will not attempt to contact you again. We hope you will say yes, or at least maybe.

_____1. Yes, I am definitely interested

_____2. Maybe. You may contact me and I will decide then.

_____3. No, I definitely do not want to be contacted again.

51770 0901

Source: https://www.industrydocuments.ucsf.edu/docs/yxb0001

IMPORTANT

You must complete this form to receive payment.

Washington University requires that this form be filled out to comply with grant regulations.

INSTRUCTIONS

If you would like to receive payment by check, mark check in the Form of Payment box. A check will be mailed to you in about two weeks. If you would rather receive cash, mark cash in the Form of Payment box. Cash can not be mailed to you; instead, you must call Cindy at 362-7071 to schedule an appointment to pick up your payment.

Please print your name, the date and your Social Security number clearly. If we cannot read your handwriting, we will not be able to pay you. Sign the form on the line above Recipient's Signature. Please check your address and make any necessary corrections.

THANK YOU FOR PARTICIPATING!

Form of Payment: Check_____

(Check one) Cash _____

Employee_____ .**

Document No._____

Date Processed ____/____/____

(for Internal Use only)

Washington University School of Medicine

Consent for Participation in Research Activities and Request for Payment

This will serve to certify that _____ is to be paid

(please print name clearly)

$15.00 for their voluntary participation in a research study for the Department of Psychiatry involving a confidential medical – psychiatric interview on ___/___/___.

(Date)

Any questions that I have about this procedure have been answered satisfactorily and I have been informed of my freedom to defer from answering any questions.

***** Note: Employees of Washington University must be paid by means of a payroll check.***

Interviewer's Signature

Social Security Number

Principal Investigator's Signature (Required for A-21)

Recipient's Signature

C. Robert Cloninger, M.D.

Principal Investigator's Name

National Health Survey

Grant or Study Name (Required for A-21)

55081

University Fund Number

51770 0902

http://legacy.library.ucsf.edu/tid/plr07a00/pdf

INSTRUCTIONS

Thank you again for completing the original National Health Study. We are currently conducting a follow-up to the National Health Study and appreciate your time in helping us with this follow-up. We think you will find this questionnaire about lifestyles and health interesting.

Although some parts of the booklet are similar to the original booklet, many sections have changed. Each section is clearly marked and each is slightly different from the others. Please read carefully the directions at the beginning of each section.

We would like you to fill out this questionnaire on your own, and we suggest you use a pencil in case you want to change an answer, but you may use a pen if you wish. Read the instructions and the questions carefully, but do not spend a lot of time deciding on the answers. There is no need to complete the questionnaire all at once, unless you want to.

When you are finished, please return the questionnaire to Washington University School of Medicine in the enclosed postage-paid envelope, or you may deliver it personally.

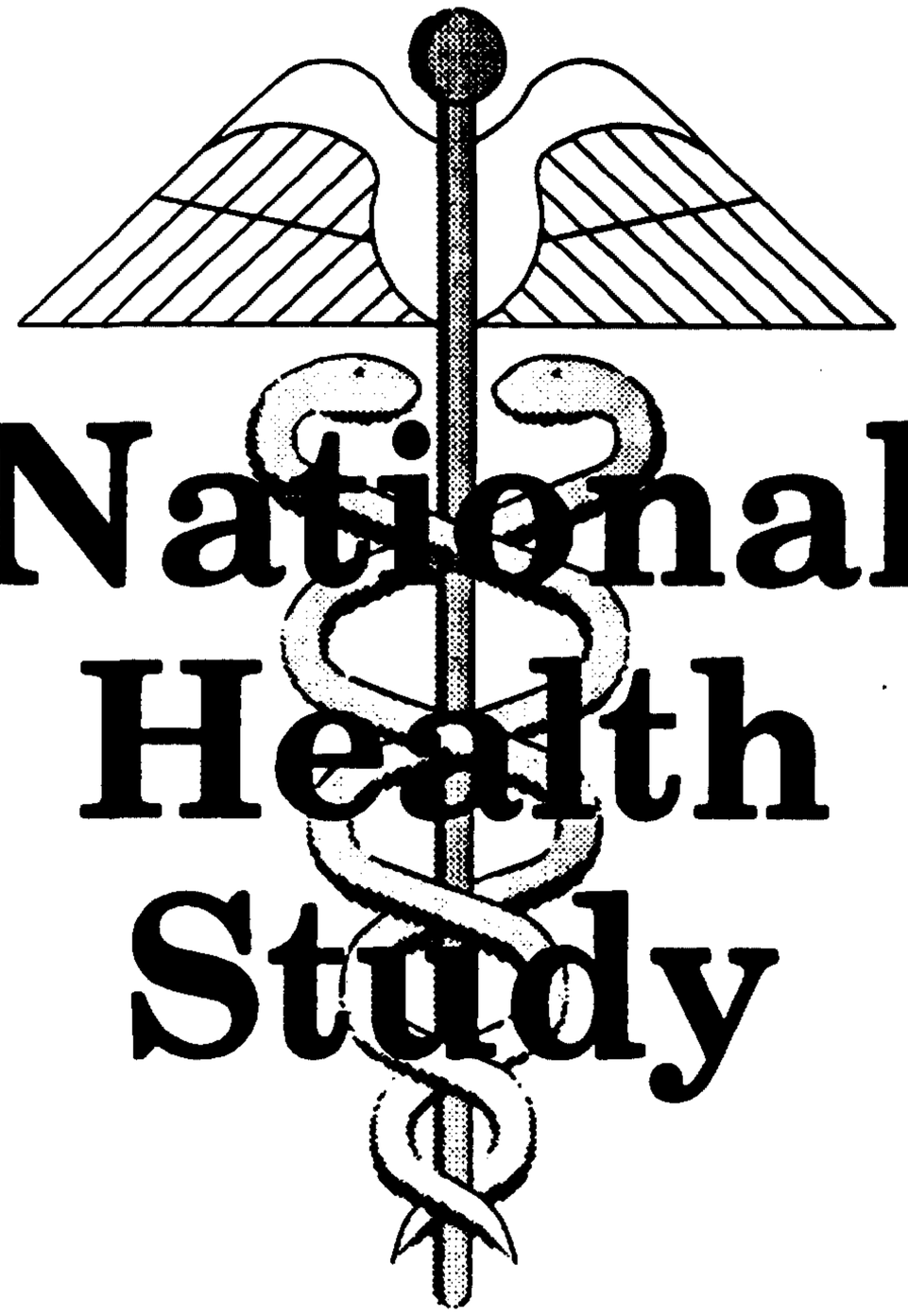
If you have any questions about the study or would like to makean appointament to deliver the questionnaire, please call Cynthia Whitehead at 314/362-7071.

THANK YOU FOR YOUR HELP!

51770 0903

http://legacy.library.ucsf.edu/tid/plr07e00/pdf

Washington
WASHINGTON·UNIVERSITY·IN·ST·LOUIS
School of Medicine



National Health Study

51770 0904

EXHIBIT
5A
11/14/97

FOR USE ONLY BY SCIENTIFICALLY SELECTED RESPONDENTS
Participation in this study is voluntary.
The information you provide will be treated as *Strictly Confidential.*

WU#_____

http://legacy.library.ucsf.edu/tid/plr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/yfxl0001

INSTRUCTIONS

Thank you for agreeing to participate in this important National Health Study.

There are five parts to this questionnaire, in addition to some general information we would like you to provide.

Each section is clearly marked and each is slightly different from the others. A brief description of the types of questions and instructions for completing them are at the beginning of each section.

We would like you to fill out this questionnaire on your own, and we suggest you use a pencil in case you want to change an answer, but you may use a pen if you wish. Read the instructions and the questions carefully, but do not spend a lot of time deciding on the answers. There is no need to complete the questionnaire all at once, unless you want to.

When you are finished, please return the questionnaire to Washington University School of Medicine in the enclosed postage-paid envelope, or you may deliver it personally.

If you have any questions about the study or where to deliver the questionnaire, please call Cynthia Whitehead at 314/362-7071.

THANK YOU FOR YOUR HELP!

51770 0905

http://legacy.library.ucsf.edu/tid/plr07a00/pdf

GENERAL INFORMATION

This section asks for some general information which will be helpful as we compile the data from this study. Please fill in the information below. If you are not sure of an exact answer, please give your best estimate.

1. Today's date _____/___/___
Month/ Day/ Year

2. Your Sex (circle): Female Male

3. Ethnic Group (circle): Black White Hispanic Other_____
(Please specify)

4. Your Age: _____ Date of Birth: _____/___/___
Month/ Day/ Year

Place of birth: _____ _____ _____
City State Zip

5. Your current marital status (Please circle appropriate letter)

Never Married	Widowed	Married	Remarried	Living Together	Living Together (Gay)	Separated	Divorced
(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)

6. How many years have you lived with your present spouse/partner? _____ years

7. How many times have you been married, including your present marriage? _____ times

8. Your education (Please circle letter of highest educational level completed):

Elementary School		*High School*		*College*	
0-7 Years	8 Years	1-3 Years	4 Years	1-3 Years	4+ Years
(A)	(B)	(C)	(D)	(E)	(F)

9. Your employment (Please circle appropriate letter):

Student	Homemaker	Unemployed	Part-time	Full-time	Retired
(A)	(B)	(C)	(D)	(E)	(F)

51770 0906

http://legacy.library.ucsf.edu/tid/plr07a00/pdf

10. Your occupation, or former occupation, if not currently in paid employment. (Please circle the number which best describes your occupation):

A. Don't know
B. Does not apply, never employed
C. Clerical/salesperson
D. Craftsperson
E. Operative/skilled laborer
F. Service Worker
G. Paraprofessional/technical
H. Professional
I. Manager
J. Farmer--100 acres of land
K. Farmer--over 100 acres
L. Farm laborer
M. Other laborer
N. Other_____
(Please specify)

11. Your religion (Please circle appropriate letter):

Catholic	Protestant (fundamentalist)	Other Protestant	Jewish	Other	None	Prefer not to answer
(A)	(B)	(C)	(D)	(E)	(F)	(G)

12. Your church attendance (Please circle appropriate letter):

More than once a week	Once a week	Once or twice a month	A few times a year	Rarely	Never
(A)	(B)	(C)	(D)	(E)	(F)

Thank you, now proceed to SECTION 1

51770 0907

http Source: http://www.library.dartmouth.edu/dlxs/dissertations/about.html

Section 1

In this section you will find statements people might use to describe their attitudes, opinions, interests, and other personal feelings. Try to describe yourself the way you usually or <u>GENERALLY</u> act and feel, not just how you are feeling right now.

Read each statement carefully and decide <u>which choice better describes you</u>, but don't spend too much time deciding on the answer.

Please answer every statement, even if you are not completely sure of the answer.

Remember there are no right or wrong answers --- just describe you own personal opinions and feelings.

Each statement can be answered TRUE or FALSE.

To answer, you only need to circle either "T" or "F" after each question. Here is an <u>example</u>:

I understand how to fill out this questionnaire.	T	F

If you understand how to fill out this questionnaire, circle the "T" to show that the statement is TRUE.

1.	I often try new things just for fun or thrills, even if most people think it is a waste of time	T	F
2.	I usually am confident that everything will go well, even in situations that worry most people.	T	F
3.	Whatever I really need always seems to be provided, even if it is not what I wanted	T	F
4.	I am often moved deeply by a fine speech or poetry.	T	F
5.	I often feel that I am the victim of circumstances.	T	F
6.	I am content to accept the failure of my best efforts	T	F
7.	I can usually accept other people as they are, even when they are very different from me	T	F
8.	I believe that miracles happen.	T	F
9.	I am quick to volunteer when there is something to be done.	T	F
10.	I enjoy getting revenge on people who hurt me.	T	F
11.	Often when I am concentrating on something, I lose awareness of the passage of time.	T	F
12.	No job is too hard for me to do my best.	T	F
13.	Often I feel that my life has little purpose or meaning	T	F
14.	I like to help find a solution to problems so that everyone comes out ahead	T	F
15.	I am a very ambitious person.	T	F
16.	I could probably accomplish more than I do, but I don't see the point in pushing myself harder than is necessary to get by.	T	F
17.	I often feel tense and worried in unfamiliar situations, even when others feel there is little to worry about.	T	F
18.	Please circle true, this is a validity item.	T	F
19.	I often do things based on how I feel at the moment without thinking about how they were done in the past.	T	F
20.	I usually do things my own way -- rather than giving in to the wishes of other people.	T	F
21.	I often find myself telling my intimate feelings to people I have just met.	T	F
22.	I often feel so connected to the people around me that it is like there is no separation between us.	T	F
23.	I generally don't like people who have different ideas from me	T	F
24.	I often wish that I didn't have to suffer as much as I do.	T	F
25.	In most situations my natural responses are based on good habits that I have developed.	T	F
26.	I would do almost anything legal in order to become rich and famous, even if I would lose the trust of many old friends.	T	F
27.	I am content to accept anything that I cannot change	T	F

51770 0908

http://legacy.library.ucsf.edu/tid/plr07a00/pdf Source: https://www.industrydocuments.ucsf.edu/docs/dxd0001

28. I am much more reserved and controlled than most people	T	F
29. I often have to stop what I am doing because I start worrying about what might go wrong	T	F
30. I like to discuss my experiences and feelings openly with friends instead of keeping them to myself	T	F
31. I am usually eager to get going on any job I have to do	T	F
32. I have less energy and get tired more quickly than most people	T	F
33. I am often called "absent-minded" because I get so wrapped up in what I am doing that I lose track of everything else	T	F
34. The harder a job is the more I like it	T	F
35. I seldom feel free to choose what I want to do	T	F
36. I often consider another person's feelings as much as my own	T	F
37. I am often described as an underachiever	T	F
38. Most of the time I would prefer to do something a little risky (like riding in an automobile over steep hills and sharp turns) rather than having to stay quiet and inactive for a few hours	T	F
39. I often avoid meeting strangers because I lack confidence with people I do not know	T	F
40. I would rather have many casual acquaintances rather than just a few close friends	T	F
41. I like to please other people as much as I can	T	F
42. I like old "tried and true" ways of doing things much better than trying "new and improved" ways	T	F
43. Usually I am not able to do things according to their priority of importance to me because of lack of time	T	F
44. I often do things to help protect animals and plants from extinction	T	F
45. I wish I could perform miracles	T	F
46. I often wish that I was smarter than everyone else	T	F
47. It gives me pleasure to see my enemies suffer	T	F
48. I am happy only when I get what I want	T	F
49. I like to be very organized and set up rules for people whenever I can	T	F

50. It is difficult for me to keep the same interests for a long time because my attention often shifts to something else	T	F
51. I am not satisfied unless I am working on something	T	F
52. Repeated practice has given me good habits that are stronger than most momentary impulses or persuasion	T	F
53. I am usually so determined that I continued to work long after other people have given up	T	F
54. I like a challenge better than easy jobs	T	F
55. I am fascinated by the many things in life that cannot be scientifically explained	T	F
56. I have many bad habits that I wish I could break	T	F
57. I often wait for someone else to provide a solution to my problems	T	F
58. I often accomplish more than people expect of me	T	F
59. I often spend money until I run out of cash or get into debt from using too much credit	T	F
60. I think I will have very good luck in the future	T	F
61. I open up quickly to other people, even if I don't know them well	T	F
62. I recover more slowly than most people from minor illnesses or stress	T	F
63. It wouldn't bother me to be alone all the time	T	F
64. The world would be a better place if no one ever suffered	T	F
65. Often I have unexpected flashes of insight or understanding while relaxing	T	F
66. I don't care very much whether other people like me or the way I do things	T	F
67. I have no complaints about my life	T	F
68. I usually try to get just what I want for myself because it is not possible to satisfy everyone anyway	T	F
69. I have no patience with people who don't accept my views	T	F
70. I don't seem to understand most people very well	T	F
71. You don't have to be dishonest to succeed in business	T	F
72. The saying "the early bird catches the worm" describes my attitude	T	F

51770 0909

http://legacy.library.ucsf.edu/tid/plr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/vtxl0001

73. I sometimes feel so connected to nature that everything seems to be part of one living organism.	T	F
74. In conversations I am much better as a listener than as a talker	T	F
75. When my work is criticized, I try harder to get it right	T	F
76. I lose my temper more quickly than most people	T	F
77. When I have to meet a group of strangers, I am more shy than most people.	T	F
78. I love to excel at everything I do	T	F
79. I am more sentimental than most people	T	F
80. I seem to have a "sixth sense" that sometimes allows me to know what is going to happen	T	F
81. I would not be happy in a job where I did not communicate with other people.	T	F
82. When someone hurts me in any way, I usually try to get even.	T	F
83. My attitudes are determined largely by influences outside my control	T	F
84. Each day I try to take another step toward my goals.	T	F
85. I often wish I was stronger than everyone else.	T	F
86. I like to think about things for a long time before I make a decision.	T	F
87. Everything that has happened to me has been good for me in the long run	T	F
88. I am more hard-working than most people	T	F
89. I often need naps or extra rest periods because I get tired so easily	T	F
90. The suffering in my life has helped me to be humble	T	F
91. I like to be of service to others	T	F
92. Regardless of any temporary problem that I have to overcome, I always think it will turn out well	T	F
93. No matter how hard a job is, I like to get started quickly	T	F
94. It is hard for me to enjoy spending money on myself, even when I have saved plenty of money	T	F
95. I usually stay calm and secure in situations that most people would find physically dangerous	T	F
96. I often do my best work under difficult circumstances	T	F

97. I like to keep my problems to myself	T	F
98. I don't mind discussing my personal problems with people whom I have known briefly or slightly.	T	F
99. I am only satisfied when I do my best, even when other people don't notice	T	F
100. I like to stay at home better than to travel or explore new places	T	F
101. I do not think it is smart to help weak people who cannot help themselves	T	F
102. Warm friendships with other people are very important to me.	T	F
103. I cannot have any peace of mind if I treat other people unfairly, even if they are unfair to me	T	F
104. People will usually tell me how they feel.	T	F
105. I often wish I could stay young forever.	T	F
106. I am usually more upset than most people by the loss of a close friend.	T	F
107. I only want to be my natural self	T	F
108. Sometimes I have felt like I was part of something with no limits or boundaries in time and space.	T	F
109. I sometimes feel a spiritual connection to other people that I cannot explain in words.	T	F
110. I try to be considerate of other people's feelings, even when they have been unfair to me in the past.	T	F
111. Now I could calmly accept almost any change in life.	T	F
112. I like it when people can do whatever they want without strict rules and regulations.	T	F
113. I would probably stay relaxed and outgoing when meeting a group of strangers, even if I were told they are unfriendly.	T	F
114. I never volunteer for anything I don't have to do	T	F
115. Usually I am more worried than most people that something might go wrong in the future	T	F
116. I usually think about all the facts in detail before I make a decision.	T	F
117. I feel it is more important to be sympathetic and understanding of other people than to be practical and tough-minded	T	F
118. I often feel a strong sense of unity with all the things around me	T	F
119. I often quit working if people aren't nice to me	T	F

51770 0910

http://legacy.library.ucsf.edu/tid/plr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/pyxl0001

120. I often wish I had special powers like Superman.	T	F
121. Other people control me too much	T	F
122. I am often described as an overachiever.	T	F
123. I like to share what I have learned with other people.	T	F
124. Religious experiences have helped me understand the real purpose of my life	T	F
125. I often learn a lot from people.	T	F
126. Repeated practice has allowed me to become good at many things that help me to be successful	T	F
127. Everything is exactly as it should be right now.	T	F
128. I am usually able to get other people to believe me, even when I know that what I am saying is exaggerated or untrue.	T	F
129. I need much extra rest, support, or reassurance to recover from minor illnesses or stress.	T	F
130. Insults really hurt my pride	T	F
131. I know there are principles for living that no one can violate without suffering in the long run.	T	F
132. I don't want to be richer than everyone else.	T	F
133. I like to go slow in starting work, even if it is easy to do.	T	F
134. I would gladly risk my own life to make the world a better place.	T	F
135. Even after thinking about something a long time, I have learned to trust my feelings more than my logical reasons	T	F
136. Sometimes I have felt my life was being directed by a spiritual force greater than any human being.	T	F
137. I am only effective doing work that I like.	T	F
138. I usually enjoy being mean to anyone who has been mean to me.	T	F
139. I have a reputation as someone who is very practical and does not act on emotion.	T	F
140. I cannot work for people who don't frequently tell me that they like what I am doing	T	F
141. It is easy for me to organize my thoughts while talking to someone.	T	F
142. I often react so strongly to unexpected news that I say or do things that I regret	T	F

143. I often get stuck in a rut, doing something unsuccessful in the same way over and over.	T	F
144. I am strongly moved by sentimental appeals (like when asked to help crippled children).	T	F
145. I usually push myself harder than most people do because I want to do as well as I possibly can.	T	F
146. It takes me a long time to warm up to other people.	T	F
147. I have so many faults that I don't like myself very much.	T	F
148. I have too little time to look for long-term solutions for my problems	T	F
149. I often wish for things that I don't have.	T	F
150. I often cannot deal with problems because I just don't know what to do	T	F
151. I often wish I could stop the passage of time	T	F
152. Now I am as thankful for my failures as for my successes.	T	F
153. I hate to make decisions based only on my first impressions.	T	F
154. I prefer spending money rather than saving it	T	F
155. I prefer to let other people do my work if I can	T	F
156. I can usually do a good job of stretching the truth to tell a funnier story or to play a joke on someone.	T	F
157. Even after there are problems in a friendship, I nearly always try to keep it going anyway	T	F
158. Even when unexpected problems occur, I keep trying to get the job done right	T	F
159. If I am embarrassed or humiliated, I get over it very quickly	T	F
160. It is extremely difficult for me to adjust to changes in my usual way of doing things because I get so tense, tired, or worried	T	F
161. When my work goes unnoticed, I become even more determined to succeed	T	F
162. I usually demand very good practical reasons before I am willing to change my old ways of doing things	T	F
163. I need a lot of help from other people to train me to have good habits.	T	F
164. I think that extra-sensory perception (ESP, like telepathy or precognition) is really possible.	T	F

51770 0911

165. If I am used to doing something a certain way, it is hard to quit even when it no longer is successful.	T	F
166. I would like to have warm and close friends with me most of the time	T	F
167. I often keep trying the same thing over and over again, even when I have not had much success in a long time.	T	F
168. I nearly always stay relaxed and carefree, even when nearly everyone else is fearful	T	F
169. I find sad songs and movies pretty boring.	T	F
170. I always try to greet people, even strangers, with a friendly smile	T	F
171. Circumstances often force me to do things against my will	T	F
172. It is hard for me to tolerate people who are different from me	T	F
173. I feel that the universe is unfolding just as it should.	T	F
174. I think that most things that are called miracles are just chance.	T	F
175. I would rather be kind than to get revenge when someone hurts me.	T	F
176. I am usually peaceful because I don't want much	T	F
177. I often become so fascinated with what I'm doing that I get lost in the moment - like I'm detached from time and place.	T	F
178. I do not think I have a real sense of purpose for my life	T	F
179. I really enjoy keeping busy	T	F
180. I try to cooperate with others as much as possible	T	F
181. I am satisfied with my accomplishments, and have little desire to do better.	T	F
182. I cannot work with people who criticize me often.	T	F
183. I often feel tense and worried in unfamiliar situations, even when others feel there is no danger at all	T	F
184. I often follow my instincts, hunches, or intuition without thinking through all the details	T	F
185. I am often successful because of my ambition and hard work.	T	F
186. Other people often think that I am too independent because I won't do what they want	T	F

187. I often feel a strong spiritual or emotional connection with all the people around me	T	F
188. Once I make up my mind about something, it is very difficult to get me to change.	T	F
189. It is usually easy for me to like people who have different values from me.	T	F
190. I try to do as little work as possible, even when other people expect more of me.	T	F
191. I am good at communicating my feelings to others.	T	F
192. Good habits have become "second nature" to me – they are automatic and spontaneous actions nearly all the time	T	F
193. I don't mind the fact that other people often know more than I do about something	T	F
194. I usually try to imagine myself "in other people's shoes", so I can really understand them.	T	F
195. I try to make sure that things will turn out as planned	T	F
196. Principles like fairness and honesty have little role in some aspects of my life	T	F
197. I am better at saving money than most people	T	F
198. I ask for little and refuse little	T	F
199. I seldom let myself get upset or frustrated: when things don't work out, I simply move on to other activities.	T	F
200. Even when most people feel it is not important, I often insist on things being done in a strict and orderly way	T	F
201. I am eager to start work on any assigned duty.	T	F
202. I feel very confident and sure of myself in almost all social situations.	T	F
203. My friends find it hard to know my feelings because I seldom tell them about my private thoughts	T	F
204. I only work well when I get a lot of praise	T	F
205. I hate to change the way I do things, even if many people tell me there is a new and better way to do it.	T	F
206. I think it is unwise to believe in things that cannot be explained scientifically	T	F
207. I am willing to make many sacrifices to be a success.	T	F
208. I like to imagine my enemies suffering	T	F
209. I am more energetic and tire less quickly than most people	T	F

51770 0912

http://legacy.library.ucsf.edu/tid/plr07a00/pdf

210. I like to pay close attention to details in *everything I do*	T	F
211. I often stop what I am doing because I get worried, even when my friends tell me everything will go well	T	F
212. I am more stubborn than most people	T	F
213. I often wish I was more powerful than everyone else	T	F
214. I usually am free to choose what I will do	T	F
215. I make a warm personal connection with most people	T	F
216. Often I become so involved in what I am doing that I forget where I am for a while	T	F
217. Members of a team rarely get their fair share	T	F
218. I wish the world was a better place than it is	T	F
219. Most of the time I would prefer to do something risky (like hang-gliding or parachute jumping) – rather than having to stay quiet and inactive for a few hours	T	F
220. Because I so often spend too much money on impulse, it is hard for me to save money – even for special plans like a vacation	T	F
221. I don't go out of my way to please other people	T	F
222. I am often upset about the way I have been treated	T	F
223. I am not shy with strangers at all	T	F
224. I often give in to the wishes of friends	T	F
225. I often drag my heels a while before starting any project	T	F
226. I spend most of my time doing things that seem necessary but not really important to me	T	F
227. I don't think that religious or ethical principles about what is right and wrong should have much influence in business decisions	T	F
228. When things don't work out at first, I am determined to work harder rather than to quit	T	F
229. I often try to put aside my own judgments so that I can better understand what other people are experiencing	T	F
230. Many of my habits make it hard for me to accomplish worthwhile goals	T	F
231. I like to strive for bigger and better things	T	F

232. I have made real personal sacrifices in order to make the world a better place – like trying to prevent war, poverty and injustice	T	F
233. I never worry about terrible things that might happen in the future	T	F
234. I often succeed because of my readiness to change with the times	T	F
235. I almost never get so excited that I lose control of myself	T	F
236. I often give up a job if it takes much longer than I thought it would	T	F
237. I like other people to know that I really care about them	T	F
238. I prefer to start conversations, rather than waiting for others to talk to me	T	F
239. Most of the time I quickly forgive anyone who does me wrong	T	F
240. I usually feel that everything is right in the world	T	F
241. My actions are determined largely by influences outside my control	T	F
242. I often have to change my decisions because I had a wrong hunch or mistaken first impression	T	F
243. I prefer to wait for someone else to take the lead in getting things done	T	F
244. I usually respect the opinions of others	T	F
245. My reputation is very important to me	T	F
246. I have had experiences that made my role in life so clear to me that I felt very excited and happy	T	F
247. It is fun for me to buy things for myself	T	F
248. I believe that I have experienced extra-sensory perception myself	T	F
249. I have often been called an "eager beaver" because of my enthusiasm for hard work	T	F
250. I believe that my brain is not working properly	T	F
251. My behavior is strongly guided by certain goals that I have set for my life	T	F
252. It is usually foolish to promote the success of other people	T	F
253. I often wish I could live forever	T	F
254. When someone points out my mistakes, I work extra hard to correct them	T	F
255. I usually like to stay cool and detached from other people		

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256. I am more likely to cry at a sad movie than most people.	T	F
257. I will not let anything get in the way of my success.	T	F
258. I recover more quickly than most people from minor illnesses or stress	T	F
259. I often break rules and regulations when I think I can get away with it	T	F
260. I won't give up what I am doing just because of a long run of unexpected failures	T	F
261. I need much more practice in developing good habits before I will be able to trust myself in many tempting situations.	T	F
262. I wish other people didn't talk as much as they do.	T	F
263. I would rather read a book than talk about my feelings with another person	T	F
264. Everyone should be treated with dignity and respect, even if they seem to be unimportant or bad.	T	F
265. I like to make quick decisions so I can get on with what has to be done.	T	F
266. I wish I had more control over everything	T	F
267. I usually have good luck in whatever I try to do	T	F
268. I am usually confident that I can easily do things that most people would consider dangerous (such as driving an automobile fast on a wet or icy road).	T	F
269. I am usually thankful, even when I don't get what I asked for.	T	F
270. I see no point in continuing to work on something unless there is a good chance of success	T	F
271. I like to explore new ways to do things	T	F
272. Please circle true; this is a validity item.	T	F
273. I enjoy saving money more than spending it on entertainment or thrills	T	F
274. Individual rights are more important than the needs of any group.	T	F
275. I have had personal experiences in which I felt in contact with a divine and wonderful spiritual power	T	F
276. No assignment is so hard that I am not eager to try my best	T	F
277. I have had moments of great joy in which I suddenly had a clear, deep feeling of oneness with all that exists	T	F

278. Good habits make it easier for me to do things the way I want.	T	F
279. Most people seem more resourceful than I am	T	F
280. Other people and conditions are often to blame for my problems	T	F
281. When I fail at something at first, I become even more determined to do a better job	T	F
282. It gives me pleasure to help others, even if they have treated me badly.	T	F
283. I often feel like I am a part of the spiritual force on which all life depends.	T	F
284. I am more concerned with enjoying the present moment -- rather than working for the future	T	F
285. Even when I am with friends, I prefer not to "open up" very much.	T	F
286. I usually can stay "on the go" all day without having to push myself.	T	F
287. If something doesn't work as I expected, I am more likely to quit than to keep going for a long time.	T	F
288. I nearly always think about all the facts in detail before I make a decision, even when other people demand a quick decision.	T	F
289. I am not very good at talking my way out of trouble when I am caught doing something wrong.	T	F
290. I would rather be alone than deal with other people's problems.	T	F
291. I am more of a perfectionist than most people	T	F
292. Whether something is right or wrong is just a matter of opinion	T	F
293. I think my natural responses now are usually consistent with my principles and long-term goals	T	F
294. I believe that all life depends on some spiritual order or power that cannot be completely explained.	T	F
295. I like to know exactly how things have been arranged.	T	F
296. I think I would stay confident and relaxed when meeting strangers, even if I were told they are angry at me	T	F
297. People find it easy to come to me for help, sympathy, and warm understanding.	T	F
298. I am slower than most people to get excited about new ideas and activities.	T	F

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299.	I want many things that I don't have	T	F
300.	I have trouble telling a lie, even when it is meant to spare someone else's feelings . .	T	F
301.	There are some people I don't like	T	F
302.	I like to be quick to respond to any request for work	T	F
303.	I don't want to be more admired than everyone else.	T	F
304.	Often when I look at an ordinary thing, something wonderful happens – I get the feeling that I am seeing it fresh for the first time.	T	F
305.	I usually meet people I like wherever I go.	T	F
306.	Most people I know look out only for themselves, no matter who else gets hurt.	T	F
307.	I usually feel tense and worried when I have to do something new and unfamiliar.	T	F
308.	I often push myself to the point of exhaustion or try to do more than I really can	T	F
309.	Some people think I am too stingy or tight with my money	T	F
310.	When I fail to master something at first, it becomes my personal challenge to succeed	T	F
311.	Reports of mystical experiences are probably just wishful thinking	T	F
312.	My will power is too weak to overcome very strong temptations, even if I know I will suffer as a consequence	T	F
313.	I want to be the best at everything I do . .	T	F
314.	I hate to see anyone suffer	T	F
315.	I know what I want to do in my life.	T	F
316.	I believe that compromise is the surest way to success	T	F
317.	I regularly take time to consider whether what I am doing is right or wrong.	T	F
318.	Things often go wrong for me unless I am very careful	T	F
319.	It is easy for other people to get close to me emotionally	T	F

320.	If I am feeling upset, I usually feel better around friends than when left alone.	T	F
321.	I don't think it is possible for one person to share feelings with someone else who hasn't had the same experiences	T	F
322.	I like surprises	T	F
323.	It often seems to other people like I am in another world because I am so completely unaware of things going on around me. .	T	F
324.	I wish I were better looking than everyone else	T	F
325.	I have lied a lot on this questionnaire. . . .	T	F
326.	My personal wants and dislikes are really unimportant.	T	F
327.	I usually stay away from social situations where I would have to meet strangers, even if I am assured that they will be friendly.	T	F
328.	I love the blooming of flowers in the spring as much as seeing an old friend again. . .	T	F
329.	I like to do a job quickly and then volunteer for more.	T	F
330.	I usually look at a difficult situation as a challenge or opportunity.	T	F
331.	People involved with me have to learn how to do things my way..	T	F
332.	I cannot accept things that are not done exactly right.	T	F
333.	Dishonesty only causes problems if you get caught.	T	F
334.	I usually feel much more confident and energetic than most people, even after minor illnesses or stress.	T	F
335.	I like to read everything when I am asked to sign any papers	T	F
336.	When nothing new is happening, I usually start looking for something that is thrilling or exciting	T	F
337.	I am usually able to find something I have in common with other people.	T	F
338.	Sometimes I get upset.	T	F
339.	Occasionally I talk about people behind their backs.	T	F

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You have just completed the longest section!

Please go on to SECTION 2.

Source: https://www.industrydocuments.ucsf.edu/docs/xyx0023

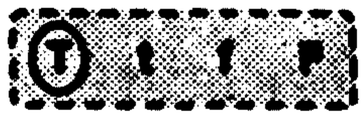
Section 2

These items consist of words and phrases that people sometimes use to describe their behavior, attitudes, and other personal characteristics. Try to describe yourself the way you usually or <u>GENERALLY</u> act and feel, not just how you are feeling right now.

Please answer every question carefully — even if you are not completely sure which answer is right for you.

For each item choose from one of the following four answers:

T	t	f	F
Definitely True	Probably True or Mostly True	Probably False or Mostly False	Definitely False

So, if the item is definitely true for you, then circle the "T" like this: 

If the item is probably or mostly true (more true than false), then you would circle "t" like this: 

	T Definitely True	t Probably True or Mostly True	f Probably False or Mostly False	F Definitely False
1. Dependable, reliable.	T	t	f	F
2. Lose sleep over worries	T	t	f	F
3. Do things that surprise and puzzle people. . .	T	t	f	F
4. Cheerful, sunny disposition.	T	t	f	F
5. Not easily upset	T	t	f	F
6. Talented, gifted	T	t	f	F
7. Don't talk much, uncommunicative.	T	t	f	F
8. Prone to have bad dreams.	T	t	f	F
9. Conventional	T	t	f	F
10. Do things on the spur of the moment	T	t	f	F
11. Exceptional, special.	T	t	f	F
12. Considerate, gentle	T	t	f	F
13. Warm, friendly	T	t	f	F
14. Dangerous to others, harmful	T	t	f	F
15. Naively enthusiastic	T	t	f	F

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http://legacy.library.ucsf.edu/tid/pkr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/tpvj0001

	T Definitely True	t Probably True or Mostly True	f Probably False or Mostly False	F Definitely False
16. Others think I am quarrelsome and contentious	T	t	f	F
17. Quiet	T	t	f	F
18. Careful and thorough in making decisions, deliberate	T	t	f	F
19. Laugh easily	T	t	f	F
20. Sophisticated	T	t	f	F
21. Reserved, distant	T	t	f	F
22. Agreeable, willing to accommodate	T	t	f	F
23. Relaxed, low-key	T	t	f	F
24. Often feel guilty for no reason	T	t	f	F
25. Do not use my imagination much	T	t	f	F
26. Dislike it when people use foul language	T	t	f	F
27. Make it a point to be logical and reasonable	T	t	f	F
28. Get along with almost everyone	T	t	f	F
29. Feel used by others	T	t	f	F
30. Important, significant	T	t	f	F
31. Bullying, threatening	T	t	f	F
32. Elegant, refined	T	t	f	F
33. Easy on others, lenient	T	t	f	F
34. Have some rather wild ideas	T	t	f	F
35. Fair-minded, just	T	t	f	F
36. Flawless, no real shortcomings	T	t	f	F
37. Rather put up a fight than make a concession	T	t	f	F
38. Average, unremarkable	T	t	f	F
39. Disgusting, sickening	T	t	f	F
40. Consistent, predictable	T	t	f	F
41. Strong, forceful	T	t	f	F
42. Easily startled	T	t	f	F
43. Lively, animated	T	t	f	F
44. Stupid	T	t	f	F
45. Often irritated by minor setbacks	T	t	f	F
46. Of high quality	T	t	f	F

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	T Definitely True	t Probably True or Mostly True	f Probably False or Mostly False	F Definitely False
47. Want my family and friends to be well-behaved at parties and other social events. .	T	t	f	F
48. Often feel betrayed by others	T	t	f	F
49. Do not like to have detailed plans.	T	t	f	F
50. Tough, uncompromising	T	t	f	F
51. Talkative.	T	t	f	F
52. Like things to be a bit disorganized and chaotic	T	t	f	F
53. Prefer to be alone.	T	t	f	F
54. Deserve respect and recognition.	T	t	f	F
55. Playful.	T	t	f	F
56. Unselfish, generous	T	t	f	F
57. Skilled, highly qualified.	T	t	f	F
58. Apt to give in to avoid a disagreement	T	t	f	F
59. Can put worries out of my mind	T	t	f	F
60. Sociable, gregarious.	T	t	f	F
61. Deliver what I promise	T	t	f	F
62. Vicious, nasty.	T	t	f	F
63. Have a natural respect for people in positions of authority.	T	t	f	F
64. Carefree, lighthearted	T	t	f	F
65. Do not like a lot of people.	T	t	f	F
66. Bothered by painful memories	T	t	f	F
67. Do things in an orderly and systematic manner.	T	t	f	F
68. Noble	T	t	f	F
69. Often jumpy and jittery	T	t	f	F
70. Unyielding, unbending.	T	t	f	F
71. Curious, inquisitive	T	t	f	F
72. Deserve to be disliked.	T	t	f	F
73. Hold traditional values and beliefs	T	t	f	F

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/bxjl0001

	T Definitely True	t Probably True or Mostly True	f Probably False or Mostly False	F Definitely False
74. Awful, terrible	T	t	f	F
75. Interested in others	T	t	f	F
76. Stubborn, obstinate	T	t	f	F
77. An ordinary, everyday person	T	t	f	F
78. Quick to feel embarrassed over small mistakes	T	t	f	F
79. Wicked, evil	T	t	f	F
80. Get into arguments, argumentative	T	t	f	F
81. Have wide-ranging interests	T	t	f	F
82. Vigorous, energetic	T	t	f	F
83. Deserve to be admired	T	t	f	F
84. Easily deceived, misled	T	t	f	F
85. Influential, have status	T	t	f	F
86. Sarcastic, scornful	T	t	f	F
87. Peppy, spirited	T	t	f	F
88. High-ranking, powerful	T	t	f	F
89. Imaginative, creative	T	t	f	F
90. Rough, violent	T	t	f	F
91. Do not worry about little things	T	t	f	F
92. Without equal, matchless	T	t	f	F
93. Do not hide my views, will speak out	T	t	f	F
94. Disciplined, self-controlled	T	t	f	F
95. Different, unlike others	T	t	f	F
96. Don't like to complain about poor service or treatment	T	t	f	F
97. Steadfast, firm	T	t	f	F
98. Feelings are easily hurt	T	t	f	F
99. Insane, crazy	T	t	f	F
100. Straightforward, forthright	T	t	f	F
101. Progressive, favor social reform	T	t	f	F
102. Deceitful, two-faced	T	t	f	F

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Source: https://www.dotsity/documents/ucsf.edu/docs/wxlh0111

	T Definitely True	t Probably True or Mostly True	f Probably False or Mostly False	F Definitely False
103. Keep belongings neat and tidy	T	t	f	F
104. Politically radical, hold revolutionary views	T	t	f	F
105. Prompt, punctual, get things done on time	T	t	f	F
106. Don't let many things bother or frustrate me	T	t	f	F
107. Cautious, circumspect	T	t	f	F
108. Often find myself on the other side of an argument	T	t	f	F
109. Believe that strict discipline at home would prevent most of the crime in society today	T	t	f	F
110. Deserve disapproval	T	t	f	F
111. Stay calm in an emergency	T	t	f	F
112. Affectionate, loving	T	t	f	F
113. Quick to blame myself	T	t	f	F
114. Odd, peculiar	T	t	f	F
115. Don't show feelings, undemonstrative	T	t	f	F
116. Impressive, remarkable	T	t	f	F
117. Headstrong, willful	T	t	f	F
118. Unusual, unconventional	T	t	f	F
119. Decent	T	t	f	F
120. Like to please others	T	t	f	F
121. Excellent, first-rate	T	t	f	F
122. Want to have a good reputation in my community	T	t	f	F
123. Dislike arguments and conflict	T	t	f	F
124. Prone to feel threatened and helpless	T	t	f	F
125. Well-organized	T	t	f	F
126. Deserve to be hated	T	t	f	F
127. Like to improvise, "play things by ear"	T	t	f	F
128. Humorless, dry	T	t	f	F

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	T Definitely True	t Probably True or Mostly True	f Probably False or Mostly False	F Definitely False
129. Nervous, high-strung	T	t	f	F
130. Dutiful, carry out obligations	T	t	f	F
131. Cruel, mean	T	t	f	F
132. Believe that most parents are too permissive, let their children get away with too much	T	t	f	F
133. Do not trust a lot of people	T	t	f	F
134. Outstanding, superior	T	t	f	F
135. Like to do things by the rules	T	t	f	F
136. Uninterested in others, indifferent	T	t	f	F
137. Often feel sorry for myself	T	t	f	F
138. Immoral	T	t	f	F
139. Thrifty, frugal	T	t	f	F
140. Strange	T	t	f	F
141. Quickly get over an embarrassing experience	T	t	f	F
142. Spontaneous, impulsive	T	t	f	F
143. Depraved, perverted	T	t	f	F
144. Try to avoid difficulties with other people	T	t	f	F
145. Liked, popular	T	t	f	F
146. Easily manipulated by others	T	t	f	F
147. Mentally disturbed, sick	T	t	f	F
148. Thought of as old-fashioned by some people	T	t	f	F
149. Conscientious, scrupulous	T	t	f	F
150. Unpleasant and disagreeable if I have to	T	t	f	F
151. Not exceptional, not that special	T	t	f	F
152. Able to experience real joy and excitement	T	t	f	F
153. Weird	T	t	f	F

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Source: https://www.industrydocuments.ucsf.edu/docs/MXD001

	T Definitely True	t Probably True or Mostly True	f Probably False or Mostly False	F Definitely False
154. Fast and careless rather than slow and plodding	T	t	f	F
155. Skeptical, do not believe anything quickly.	T	t	f	F
156. Like to be with people, sociable.	T	t	f	F
157. Often stop one activity before completing it and start another	T	t	f	F
158. Treacherous, disloyal	T	t	f	F
159. Conservative.	T	t	f	F
160. Polite, tactful.	T	t	f	F
161. Like to have a place for everything and everything in its place.	T	t	f	F

Two very short sections follow this one.

Please go on ... you're almost finished.

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Section 3

Below is a list of the ways you might have felt or behaved. Please circle how often you have felt this way <u>DURING THE PAST WEEK</u>.

0	1	2	3
Rarely or None of the Time (less than 1 day)	Some or a Little of the Time (1-2 days)	Occasionally or a Moderate Amount of Time (3-4 days)	Most or All of the Time (5-7 days)

1.	I was bothered by things that usually don't bother me.	0	1	2	3
2.	I did not feel like eating; my appetite was poor	0	1	2	3
3.	I felt that I could not shake off the blues even with help from my family or friends	0	1	2	3
4.	I felt that I was just as good as other people	0	1	2	3
5.	I had trouble keeping my mind on what I was doing	0	1	2	3
6.	I felt depressed.	0	1	2	3
7.	I felt that everything I did was an effort	0	1	2	3
8.	I felt hopeful about the future.	0	1	2	3
9.	I thought my life had been a failure	0	1	2	3
10.	I felt fearful	0	1	2	3
11.	My sleep was restless	0	1	2	3
12.	I was happy.	0	1	2	3
13.	I talked less than usual	0	1	2	3
14.	I felt lonely.	0	1	2	3
15.	People were unfriendly	0	1	2	3
16.	I enjoyed life	0	1	2	3
17.	I had crying spells	0	1	2	3
18.	I felt sad.	0	1	2	3
19.	I felt that people dislike me	0	1	2	3
20.	I could not get "going"	0	1	2	3

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http://legacy.library.ucsf.edu/tid/ole07e00/pdf

Section 4

Below is a list of questions about your use of alchohol. Please answer by circling "Yes" or "No."

1.	Do you feel you are a normal drinker? (By normal we mean you drink less than or as much as most other people.)	YES	NO
2.	Does your wife, husband, a parent, or other near relative ever worry or complain about your drinking?	YES	NO
3.	Do you ever feel guilty about your drinking?	YES	NO
4.	Do friends or relatives think you are a normal drinker?	YES	NO
5.	Are you able to stop drinking when you want to?	YES	NO
6.	Have you ever attended a meeting of Alcoholics Anonymous?	YES	NO
7.	Has drinking ever created problems between you and your wife, husband, a parent, or other near relative	YES	NO
8.	Have you ever gotten into trouble at work because of drinking?	YES	NO
9.	Have you ever neglected your obligations, your family, or your work for two or more days in a row because you were drinking?	YES	NO
10.	Have you ever gone to anyone for help about your drinking?	YES	NO
11.	Have you ever been in a hospital because of drinking?	YES	NO
12.	Have you ever been arrested for drunken driving, driving while intoxicated, or driving under the influence of alcoholic beverages?	YES	NO
13.	Have you ever been arrested, even for a few hours, because of other drunken behavior?	YES	NO

The last section is SECTION 5 which asks questions about your general health. There are a variety of questions and different ways to record your answers. There are instructions to guide you.

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Section 5

General Health Information

1. In general, how would you describe your health? (Check only one number below.)

   _____ 1. Excellent
   _____ 2. Very Good
   _____ 3. Good
   _____ 4. Fair
   _____ 5. Poor

2. How much bodily pain have you had during the past four weeks? (Check only one number below.)

   _____ 1. None
   _____ 2. Very Mild
   _____ 3. Mild
   _____ 4. Moderate
   _____ 5. Severe

3. How often have you ever been bothered by pain in the following parts of your body? (Circle only one number on each line.)

	1 Rarely or Never	2 Infrequently	3 Frequently	4 Very Frequently
a. Head	1	2	3	4
b. Abdomen	1	2	3	4
c. Back	1	2	3	4
d. Joints	1	2	3	4
e. Arms or legs	1	2	3	4
f. Chest	1	2	3	4
g. Other	1	2	3	4

4. When you are experiencing pain, how often do you respond in each of the following ways? (Circle only one number on each line.)

	1 Rarely or None of the Time	2 A Little of the Time	3 Much of the Time	4 Nearly Always
a. Suffer in silence	1	2	3	4
b. Take medication	1	2	3	4
c. Tell other people	1	2	3	4
d. See a doctor	1	2	3	4
e Change plans	1	2	3	4
f. Rest and relax	1	2	3	4
g. Ignore it and go on	1	2	3	4

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf

5. How often have you ever been bothered by indigestion or stomach problems other than pain? (Circle only one number on each line.)

	1 Rarely or Never	2 Infrequently	3 Frequently	4 Very Frequently
a. Nausea	1	2	3	4
b. Diarrhea	1	2	3	4
c. Bloating or Gas	1	2	3	4
d. Vomiting	1	2	3	4
e. Constipation	1	2	3	4

For each of the following questions, please circle the number that comes closest to the way you have been feeling <u>DURING THE PAST MONTH</u>. (Circle only one number on each line.)

1 None of the Time	2 A Little of the Time	3 Some of the Time	4 A Good Bit of the Time	5 Most of the Time	6 All of the Time

	1 None of the Time	2 A Little of the Time	3 Some of the Time	4 A Good Bit of the Time	5 Most of the Time	6 All of the Time
6. How much of the time, during the past month, has your health limited your social activities (like visiting with friends or close relatives)?	1	2	3	4	5	6
7. How much of the time, during the past month, have you been a very nervous person?	1	2	3	4	5	6
8. During the past month, how much of the time, have you felt calm and peaceful?	1	2	3	4	5	6
9. How much of the time, during the past month, have you felt down-hearted and blue?	1	2	3	4	5	6
10. During the past month, how much of the time, have you been a happy person?	1	2	3	4	5	6
11. How often, during the past month, have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6

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Please answer the following questions by circling "Yes" or "No."

12. Have you ever smoked cigarettes?	YES	NO
13. Have you ever smoked a pack or more of cigarettes daily?	YES	NO
14. Have you smoked any cigarettes during the past six months?	YES	NO
15. Have you ever gone on eating binges in which you felt that you could not control how much or what you ate?	YES	NO
16. Have you ever tried to prevent gaining weight after you ate too much by purging (like making yourself vomit or taking laxatives)?	YES	NO
17. Have you ever attempted suicide?	YES	NO
18. Have you ever taken tranquilizers or other medications for your nerves?	YES	NO
19. Have you ever been treated by a psychiatrist or other mental health counsellor?	YES	NO
20. Have you ever been hospitalized because of a nervous breakdown or mental health problems?	YES	NO
21. Have you ever had such a strong fear of specific objects or situations that you avoided them (like heights, flying, blood, or some animals)?	YES	NO
22. Have you ever had such a fear of crowds or speaking in front of people that you avoided them?	YES	NO
23. Have you ever had panic attacks in which you thought you were having a heart attack or were about to die, but doctors said that it was really anxiety or nervousness?	YES	NO

24. Has your health kept you from working at a job, doing work around the house, or going to school?

_____ 1. Yes, for more than 2 years
_____ 2. Yes, for less than 2 years and more than 3 months
_____ 3. Yes, for 3 months or less
_____ 4. No

25. Please circle the number that best describes whether each of the following statements is true or false for you. (Circle only one number on each line.)

	1 Definitely True	2 Mostly True	3 Not Sure	4 Mostly False	5 Definitely False
a. I am somewhat ill.	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. My health is excellent	1	2	3	4	5
d. I have been feeling bad lately	1	2	3	4	5
e. I have been sickly most of my life	1	2	3	4	5

When you have completed the survey, please return it to Washington University School of Medicine in the enclosed, prepaid envelope, or you may deliver it personally. Please call Cynthia Whitehead (362-7071) with questions.

THANK YOU!

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Washington
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School of Medicine

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EXHIBIT
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Original Contributions

Predicting Smoking Cessation

Who Will Quit With and Without the Nicotine Patch

Susan L. Kenford; Michael C. Fiore, MD, MPH; Douglas E. Jorenby, PhD; Stevens S. Smith, PhD; David Wetter, MS; Timothy B. Baker, PhD

Objective.—To identify predictors of smoking cessation success or failure with and without transdermal nicotine patch treatment.

Design.—Two independent randomized, double-blind, placebo-controlled studies using the nicotine patch assessing outcome at the end of treatment and at 6-month follow-up; each study used a different mode of adjuvant counseling.

Patients.—Subjects were daily smokers (≥15 cigarettes per day), aged 21 to 65 years with expired air carbon monoxide levels of at least 10 ppm, and motivated to quit. Eighty-eight subjects participated in study 1, and 112 subjects participated in study 2.

Intervention.—Study 1 consisted of 8 weeks of 22-mg nicotine patch therapy with intensive group counseling. Study 2 consisted of 4 weeks of 22-mg nicotine patch therapy and 2 weeks of 11-mg nicotine patch therapy with brief individual counseling.

Main Outcome Measures.—The prediction of smoking cessation (at end of treatment and after 6 months) based on pretreatment and intratreatment measures in smokers using active or placebo nicotine patches.

Results.—Pretreatment markers, such as the Fagerstrom Tolerance Questionnaire score, number of cigarettes smoked per day, years smoked, expired air carbon monoxide level, or baseline blood nicotine and cotinine levels, showed no consistent relationship with successful smoking cessation across both studies. Of the intratreatment markers examined, withdrawal severity and nicotine replacement levels also were not consistently predictive of cessation success. However, any smoking during the second week of treatment was a consistent and powerful predictor of failure at the end of treatment and after 6 months. Among active nicotine patch patients who smoked at all during week 2 after quitting, 83% and 97% (studies 1 and 2, respectively) were smoking at 6-month follow-up. Conversely, abstinence during the second week of treatment predicted successful smoking cessation. Among active nicotine patch patients who were totally abstinent during week 2 after quitting, 46% and 41% (studies 1 and 2, respectively) were abstinent at 6-month follow-up. Of all nicotine patch patients in both studies who were smoking at 6-month follow-up, 74% began smoking during week 1 or 2. Among all placebo patch patients who were smoking at 6-month follow-up, 86% began smoking during week 1 or 2.

Conclusions.—Smoking status (abstinent or smoking) during the first 2 weeks of nicotine patch therapy, particularly week 2, was highly correlated with clinical outcome and can serve as a powerful predictor of smoking cessation. Early smoking behavior also predicted outcome among placebo patch users. Traditional measures of dependence are not consistently predictive of cessation success. Clinicians are advised to emphasize the importance of total abstinence after a quit attempt and to follow-up with patients within the first 2 weeks of quitting; smoking during this critical time should be assessed and treatment may be altered as appropriate.

(*JAMA.* 1994;271:589-594)

From the Center for Tobacco Research and Intervention (Ms Kenford, Drs Fiore, Jorenby, Smith, and Baker, and Mr Wetter) and the Section of General Internal Medicine, Department of Medicine (Drs Fiore and Jorenby), University of Wisconsin Medical School, and the University of Wisconsin Comprehensive Cancer Center (Drs Fiore, Jorenby, and Baker), Madison; and Department of Psychology, University of Wisconsin, Madison (Ms Kenford, Drs Smith and Baker, and Mr Wetter). Drs Fiore, Jorenby, Smith, and Baker, Ms Kenford, and Mr Wetter have conducted research funded in part by CIBA-GEIGY Corp, Edison, NJ; Elan Pharmaceuticals Ltd, Athlone, Ireland; and Lederle Laboratories, Wayne, NJ. Dr Fiore has also received honoraria for educational activities from CIBA-GEIGY Corp, Lederle Laboratories, Marion Merrell Dow Inc, Kansas City, Mo, and Parke-Davis, Morris Plains, NJ.

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NUMEROUS clinical trials have shown that the transdermal nicotine patch system helps people quit smoking.[1] Quit rates, however, vary widely across these trials. This may be due in part to the marked heterogeneity of smokers in the United States today. If one could identify those smokers likely to succeed or fail with or without nicotine patch treatment, it would be possible to make treatment decisions on a more rational basis and increase each patient's odds of quitting successfully.

For example, smokers judged to be at risk for failure might be given a more potent adjuvant treatment, such as intensive group counseling, to boost treatment effectiveness.[2] Other smokers might be switched to a wholly different treatment, such as nicotine fading or aversive smoking.[3]

Despite much research, accurate and consistent predictors of successful smoking cessation have not been identified. Variables that have proven predictive in some studies do not predict in others, and when predictive relations are found, they are modest. For example, gender has been found to predict treatment success in some studies[4,5] but not in another.[6] Similarly, measures that are hypothesized to reflect nicotine dependence (eg, number of cigarettes smoked per day, blood nicotine levels, and expired air carbon monoxide [CO_2] levels) have predicted treatment success weakly and inconsistently.[7,8] One reported measure of nicotine dependence, the Fagerstrom Tolerance Questionnaire[9] has predicted long-term success in some studies[8,10] but has not been consistently related to outcome among nicotine patch users.[11,12] The inconsistency in predictive relations suggests that the accuracy and sensitivity of any given predictor is affected by factors that vary from study to study, such as the target population and type of cessation treatment.

We examined predictors of treatment success and failure among smokers with and without the nicotine patch. The research included two studies with two independent samples of smokers. Moreover, two different adjuvants were used

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with *nicotine* patch therapy and placebo patch therapy: (1) intensive group counseling and (2) brief individual counseling. Independent samples and different types of adjuvants provided the opportunity to assess the generalizability of our findings.

To identify predictors of successful cessation with and without the nicotine patch, we assessed a number of variables that could be quickly and easily measured by a clinician and therefore would have broad clinical utility. We evaluated measures collected prior to quitting (pretreatment variables) and early in the quitting attempt (intratreatment variables).

METHODS

Two studies using nicotine patch therapy and two different modes of adjuvant therapy were conducted sequentially. In study 1, patch therapy was paired with state-of-the-art intensive group counseling; in study 2, patch therapy was paired with brief individual counseling that could be conducted in a clinician's office. The methods used in both studies and efficacy results are described in more detail elsewhere.[2]

Subjects

Subjects were recruited through media announcements in Madison, Wis, a city of 190 700 residents. Inclusion criteria consisted of age 21 to 65 years, a history of smoking at least 15 cigarettes per day during the past year, expired CO_a level of at least 10 ppm (as determined at screening), and motivation to quit smoking. Exclusion criteria included presence of cardiovascular disease, pregnancy or lactation, regular use of psychotropic drugs, current symptomatic psychiatric disorder, alcohol or other drug abuse, chronic dermatologic disorders, and/or use of any experimental medication within the past 30 days. Eighty-eight subjects participated in study 1, and 112 subjects participated in study 2.

Study Designs

After enrollment, the subjects and the clinician agreed on a quit date. Subjects were told to stop smoking on this date at which time nicotine patch and adjuvant counseling treatments commenced. On the quit date and once per week during the treatment period the following data were gathered at the clinic site: self-reported smoking status for the previous week (confirmed by expired CO_a assay), vital signs, and questionnaire and study drug information. Between visits, subjects kept a smoking diary each day that contained an eight-item withdrawal survey.[13] Serum samples for nicotine and cotinine were collected at a screening visit before the quit date and at 4 weeks following the quit date. Both studies were double blinded and placebo controlled.

Study 1 consisted of 8 weeks of 22-mg nicotine patch therapy (or equivalent placebo patch), and study 2 consisted of 6 weeks of nicotine patch therapy—4 weeks of 22-mg patch therapy followed by 2 weeks of 11-mg patch therapy (or placebo). In both studies, counseling sessions occurred for 8 weeks, and subjects were contacted at 6 months following their quit dates to determine their smoking status. Self-report was confirmed by expired CO_a assay.

Six-month follow-up data were used to assess predictors of success and failure because the nicotine patch was licensed by the Food and Drug Administration at this end point of study 1, and we wanted to prevent confounding of results due to the extraordinarily high rates of off-study prescription patch use immediately after licensing.

Transdermal Nicotine

The transdermal nicotine delivery system (PRO*STEP*, Lederle Laboratories, Wayne, NJ) used in these studies was a hydrogel matrix reservoir containing nicotine. The patch was applied once a day, worn for 24 hours, and delivered a total absorbed dose of either 22 mg or 11 mg of nicotine. Placebo patches contained no nicotine. Active patches and placebo patches were supplied by Elan Pharmaceuticals Ltd, Athlone, Ireland. While a comparison of pharmacokinetic properties shows differences between the different brands of patches across the initial days of treatment, within 3 days all brands achieve comparable nicotine levels and maintain these throughout treatment.

Adjuvant Treatment

In the group counseling intervention used in study 1, groups of eight to 12 members met for approximately 60 minutes per week for 8 weeks. Sessions were designed to provide information in a supportive atmosphere and teach coping skills appropriate to the subjects' place in the quitting process. This was designed to be a high-intensity counseling intervention. Individual counseling in study 2 consisted of weekly meetings for 8 weeks with individual subjects. Sessions lasted 10 to 20 minutes and targeted topics relevant to the individual's place in the quit process. This counseling was designed to be a moderate-intensity counseling intervention.

Both counseling interventions stressed the importance of abstinence, along with the identification of high-risk situations and potential coping behaviors. Both counseling interventions were conducted by psychologists or psychology graduate students who followed a tre manual developed for each study

Statistical Analyses

Baseline subject characteristic two groups (active patch vs p patch) were evaluated with two independent-group *t* tests for c ous-level dependent variables; χ of independence were comput categorical outcome variables. F tinuous variables displaying sign heterogeneity of variance, separa ance independent-group *t* test computed. Efficacy was tested tests of independence. The re among pretreatment measures tine dependence and intratre measures (blood nicotine and c levels and withdrawal severity evaluated with Pearson product-r correlations. Prediction of end-o ment abstinence or smoking fi tratreatment abstinence or smok examined both descriptively (b tabulation) and by means of odd (ORs) calculated separately fo patch subjects and placebo pat jects in each study. Additional jects classified as smoking at 6 (relapsers) were examined to de what percentage of subjects r smoking at each week of patc ment. We use the categorical abstinence or smoking as our ma come variable because it is the of chief clinical importance. All a were conducted on an intent-to-t sis with those unavailable for fo or without biochemical confirm abstinence classified as smoker

RESULTS

Study 1

Table 1 depicts the baseline teristics of subjects in the activ and placebo group. No statistic nificant differences were noted the two groups. Of the 88 subje were enrolled and randomized, pleted the 8-week active tr phase of the study. Of these, one in the placebo patch group used gum throughout the study and cluded from all analyses. Of the failed to complete the active tr phase (the first 8 weeks on st were using placebo patches, and using an active patch.

Efficacy

Abstinence was defined as a port of zero cigarettes smoke preceding 7 days confirmed b pired CO_a value of less than 10 the end of patch therapy (8 w active patch subjects (59.1%) w

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as abstinent, while 17 placebo patch
ects (39.5%) were abstinent
f=1]=3.3; *P*=.07). Of the 87 study
ects, biochemical confirmation of
king status was available for 62 at
-month follow-up mark. Of the re-
ing 25 subjects, five refused to be
viewed, 11 failed to complete treat-
, and nine were unavailable for fol-
up. At 6 months, 15 (34.1%) of 44
e patch subjects were abstinent,
pared with nine (20.9%) of 43 pla-
patch subjects (χ^2[*df*=1]=1.9; *P*=.17).
ival analyses indicated statistically
ficant (*P*<.05) lower relapse among
e patch subjects during the 6-month
w-up period.[2]

dy 2

ble 1 depicts the baseline charac-
tics of subjects in the active group
placebo group. The two groups did
differ reliably on any of these char-
ristics. Of the 112 subjects who were
lled and randomized, 79 completed
reatment phase of the study. Of the
ho failed to complete the treatment
e (the first 6 weeks on study), 18
using placebo patches, and 15 were
active patches.

acy

bstinence was defined as in study 1.
he end of patch therapy (6 weeks),
ctive patch subjects (36.8%) were
inent, while 11 placebo patch sub-
s (20.0%) were abstinent (χ^2[*df*=1]=
P=.05). Of the 112 subjects who par-
ated in this study, biochemical veri-
ion of self-reported smoking status
obtained for 72 at the 6-month fol-
up mark. Of the remaining 40 sub-
s, 33 failed to complete treatment,
seven were unavailable for follow-
At this time, 10 (17.5%) of 57 active
h subjects were abstinent, while only
(7.3%) of 55 placebo patch subjects
e abstinent (χ^2[*df*=1]=2.7; *P*=.10).
ival analysis indicated statistically
ificant (*P*<.05) lower relapse among
ve patch subjects during the 6-month
w-up period.[2]
aseline characteristics did not differ
bly across the two studies. The dif-
nce in attrition and efficacy seen be-
en the two studies is hypothesized to
elated to the nature of the adjuvant
tments (eg, group vs individual coun-
g and length of treatment sessions).

treatment Measures

aseline expired CO_2 level, blood nico-
and cotinine levels, cigarettes
ked per day, number of years
ked, and Fagerstrom Tolerance
stionnaire score were assessed in
tion to end-of-treatment abstinence
6-month abstinence. Point-biserial

Table 1.—Baseline Subject Characteristics for Study 1 and Study 2*

Variable	Study 1		Study 2	
	Active Patch (n=44)	Placebo Patch (n=43)†	Active Patch (n=57)	Placebo Patch (n=55)
Age, y	43.3 (1.5)	42.6 (1.4)	43.1 (1.2)	44.2 (1.5)
Female gender, %	56.8	55.8	68.4	67.3
Cigarettes per day	28.3 (1.1)	30.3 (1.5)	29.8 (1.3)	30.8 (1.3)
Expired air carbon monoxide level, ppm	32.3 (1.8)	31.4 (2.6)	32.5 (1.8)	34.3 (1.6)
Nicotine, ng/mL	21.0 (1.1)	18.7 (1.0)	21.0 (1.3)	21.4 (1.1)
Cotinine, ng/mL	328.2 (18.4)	261.6 (16.5)	311.3 (16.6)	311.4 (14.4)
Years smoking	25.2 (1.3)	24.3 (1.4)	24.3 (1.2)	25.9 (1.4)
Fagerstrom Tolerance Questionnaire score	7.3 (0.2)	6.9 (0.2)	7.2 (0.2)	7.7 (0.2)
Weight, kg	79.3 (2.3)	80.1 (3.2)	72.9 (2.3)	72.5 (2.3)
Beck Depression Inventory score[14]	5.1 (0.7)	5.3 (0.7)	6.3 (0.8)	6.2 (0.8)

*Standard errors are in parentheses. No group differences were significant (*P*>.05) in either study.
†One subject in the placebo patch group chewed nicotine gum throughout the patch treatment phase of the study. This subject was eliminated from all analyses.

Table 2.—Correlations Between Baseline, Week 1, and Week 4 Withdrawal Severity and Abstinence at End of Treatment and 6 Months*

Withdrawal	Study 1				Study 2			
	Abstinence at 6 Weeks		Abstinence at 6 Months		Abstinence at 6 Weeks		Abstinence at 6 Months	
	Active Patch	Placebo Patch	Active Patch	Placebo Patch	Active Patch	Placebo Patch	Active Patch	Placebo Patch
Baseline	−.36† (40)	.06 (36)	−.36† (40)	.04 (36)	.18 (49)	−.19 (49)	.06 (49)	−.20 (49)
Week 1	−.38‡ (44)	.18 (40)	−.42‡ (44)	.15 (40)	−.02 (56)	−.13 (53)	−.04 (56)	−.13 (53)
Week 4	−.35† (43)	−.25 (34)	−.35† (43)	−.05 (34)	−.19 (51)	−.26 (38)	−.17 (51)	−.21 (38)

*Higher scores on the withdrawal measure indicate greater withdrawal symptoms. Abstinence variables are coded: 1 indicates abstinence; and 0, smoking. The number of subjects on which correlation was based is in parentheses. The number changed as a function of the availability of usable withdrawal ratings.
†*P*<.05.
‡*P*<.01.

correlations were conducted separately for active patch subjects and placebo patch subjects for each of these variables. None of these pretreatment measures showed a consistent relationship with posttreatment success across studies 1 and 2. None of the 32 correlations was statistically significant, and none exceeded −.26.

Intratreatment Measures

Precessation serum nicotine and cotinine levels have been proposed as measures of tobacco dependence and as determinants of successful smoking cessation.[15] Additionally, the degree to which pretreatment serum nicotine and cotinine levels are matched or maintained via replacement therapy may be important in determining cessation success.[16]

To examine these relations, we compared the following three measures of nicotine and cotinine with successful smoking cessation outcome among active nicotine patch users: (1) baseline blood nicotine and cotinine levels, (2) absolute blood nicotine and cotinine levels achieved during nicotine replacement treatment (as measured at week 4 of patch treatment), and (3) percentage of baseline blood nicotine and cotinine levels replaced with nicotine replacement therapy. These point-biserial correlations revealed no consistent relation with outcome. For instance, the only significant predictor of 6-month abstinence was baseline nicotine level in study 2 (point-biserial correlation=−.27) (higher baseline nicotine levels were associated with 6-month relapse). The same correlation was small and opposite in sign for study 1 (point-biserial correlation=.19).

Finally, we assessed whether the severity of withdrawal symptoms during treatment was correlated with successful cessation. A withdrawal severity index was constructed by calculating the mean score for the daily eight-item withdrawal scale. Withdrawal severity at baseline, week 1, or week 4 after quitting did not consistently correlate with abstinence (Table 2). To assess the possibility that some of these intratreatment measures were confounded by intratreatment smoking, we separately analyzed data of subjects who were completely abstinent; none of the correlations was significant.

Intratreatment Smoking

In contrast to the measures described herein, intratreatment smoking did demonstrate a consistent relationship with posttreatment success. Specifically, we analyzed the relation between intratreatment smoking by week and post-

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Table 3.—Smoking in Weeks 1 and 2 of Patch Treatment and Abstinence Status at End of Treatment and 6 Months in Active Patch Subjects

	Study 1, Active Patch Subjects (n=44)			Study 2, Active Patch Subjects (n=57)		
Abstinent in Week	No. of Subjects	Abstinence at End of Treatment, %	Abstinence at 6 Months, %	No. of Subjects	Abstinence at End of Treatment, %	Abstinence at 6 Months, %
1	27	77.8	40.7	23	65.2	39.1
2	26	76.9	46.2	22	72.7	40.9
1 and 2	22	81.8	45.5	16	75.0	50.0
Smoking in Week	No. of Subjects	Smoking at End of Treatment, %	Smoking at 6 Months, %	No. of Subjects	Smoking at End of Treatment, %	Smoking at 6 Months, %
1	17	70.6	76.5	34	82.4	97.1
2	18	66.7	83.3	35	85.7	97.1
1 or 2	22	63.6	77.3	41	78.0	95.1

Table 4.—Smoking in Weeks 1 and 2 of Patch Treatment and Abstinence Status at End of Treatment and 6 Months in Placebo Patch Subjects

	Study 1, Placebo Patch Subjects (n=43)			Study 2, Placebo Patch Subjects (n=55)		
Abstinent in Week	No. of Subjects	Abstinence at End of Treatment, %	Abstinence at 6 Months, %	No. of Subjects	Abstinence at End of Treatment, %	Abstinence at 6 Months, %
1	13	76.9	38.5	12	50.0	8.3
2	16	81.3	43.8	10	70.0	30.0
1 and 2	12	83.3	41.7	5	60.0	0
Smoking in Week	No. of Subjects	Smoking at End of Treatment, %	Smoking at 6 Months, %	No. of Subjects	Smoking at End of Treatment, %	Smoking at 6 Months, %
1	30	76.7	86.7	43	88.4	93.0
2	27	85.2	92.6	45	91.1	97.8
1 or 2	31	77.4	87.1	50	84.0	92.0

treatment cessation success. These analyses demonstrated that smoking during any week of treatment was highly and negatively associated with successful cessation.

Because it would be most useful clinically to predict long-term outcomes early in the quitting process, three time periods from the initial phase of treatment were analyzed intensively. These were (1) any smoking in the first week of treatment, (2) any smoking in the second week of treatment, and (3) any smoking in either the first or second week of treatment. Tables 3 and 4 show the relation of intratreatment smoking on short-term and long-term smoking cessation rates using these three predictor time periods. Any smoking during the first 2 weeks of treatment was highly associated with a poor prognosis. However, smoking or abstinence during week 2 was the most accurate predictor of outcome (Table 5).

Table 3 illustrates the relation between early intratreatment smoking and clinical success at the end of treatment and the 6-month follow-up mark among active nicotine patch users for each study. Smoking was defined as any tobacco use at a given time point. Among nicotine patch users, if a patient smoked at all during week 2, there was a 66.7% chance or 85.7% chance (studies 1 and 2, respectively) that the patient would be smoking at the end of treatment. This relationship was also predictive for long-term outcomes. If a patient smoked in week 2, there was an 83.3% chance or 97.1% chance (studies 1 and 2, respectively) that the patient would be smoking 6 months later. Similar findings were noted among placebo patch users (Table 4). Among placebo patch users, if a patient smoked during week 2, there was an 85.2% chance or 91.1% chance (studies 1 and 2, respectively) that the patient would be smoking at the end of treatment and a 92.6% chance or 97.8% chance (studies 1 and 2, respectively) that the patient would be smoking 6 months later.

Abstinence during week 2 was also highly predictive of both short-term and long-term abstinence. For example, among active nicotine patch users, if a patient were totally abstinent during week 2, there was a 76.9% chance and 72.7% chance (studies 1 and 2, respectively) that the patient would be abstinent at the end of treatment and a 46.2% chance and 40.9% chance (studies 1 and 2, respectively) that the patient would be abstinent 6 months later (Table 3). Among placebo patch users, if a patient were totally abstinent during week 2, there was an 81.3% chance and 70.0% chance (studies 1 and 2, respectively) that the patient would be abstinent at the end of treatment and a 43.8% chance and 30.0% chance (studies 1 and 2, respectively) that the patient would be abstinent 6 months later (Table 4).

We examined the issue of whether amount of smoking in week 2 added to the predictive validity of our prediction rule. The results of a variety of analyses suggested that including information about the amount of smoking did not alter the predictive accuracy of the rule. Another test of the accuracy of a prediction rule is to determine the proportion of treatment failures the rule identifies—ie, of all subjects smoking at follow-up, what percentage smoked by week 2? Among active nicotine patch users in studies 1 and 2, respectively, of those smoking at 6 months, 59% and 83% had first smoked by the end of week 2 (74% across both studies; Figure). Among placebo patch users in studies 1 and 2, respectively, of those smoking at 6 months, 79% and 90% had first smoked by the end of week 2 (86% across both studies; Figure).

Odds ratios constitute another index of association between early smoking and long-term outcome and reflect the classification power of a prediction rule (ratio of correct to incorrect decisions yielded by the prediction rule). When smoking in week 2 of treatment was used as a marker for outcome among nicotine patch users, successful prediction was greatly enhanced at end of treatment (OR, 6.7 and 16.0 for studies 1 and 2, respectively) and at six months (OR, 4.3 and 23.5 for studies 1 and 2, respectively) (Table 5). Although smoking during any time within the first 2 weeks is predictive of failure to quit, the ORs demonstrate that the week 2 rule is associated with the most accurate predictions and the least number of misclassifications. The power of the week 2 rule to detect the observed association with 6-month outcome was .53 in study 1 and .95 in study 2. Similar findings are ob-

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when the ORs are calculated for o patch subjects (Table 5). Addi- y, ϕ coefficients (a correlation co- nt for two dichotomous variables) decision rule for each time point statistically significant.

ally, we recomputed the ORs after ically controlling for a variety of otential predictor variables. In par- we examined the relation between 2 smoking and abstinence, both at treatment and at 6-month follow- er controlling for measures of physi- pendence (Fagerstrom Tolerance ionnaire score, pretreatment blood e level, number of cigarettes d pretreatment, and pretreatment d CO_a level) and withdrawal dur- e first week of treatment. These es revealed that in all cases the ed ORs were actually higher than spective unadjusted ORs.

ction of Week 2 Smoking

ause smoking abstinence in week such an accurate predictor of long- success, we performed simulta- logistic regression analyses to fy predictors of week 2 smoking. rticular, we examined the relation ek 2 smoking and a variety of other tor variables: withdrawal sever- week 1, pretreatment Fagerstrom ance Questionnaire score, pretreat- blood nicotine level, pretreatment d CO_a level, and mean number of ttes smoked daily at pretreatment. analyses revealed that no vari- redicted week 2 smoking in study two did in study 2: pretreatment rstrom Tolerance Questionnaire and pretreatment blood nicotine However, their level of associa- with week 2 smoking was low, with alue exceeding .19. Therefore, no ble consistently and significantly cted week 2 smoking across both es 1 and 2, and when associations found, they were low.

dictive accuracy of the st of the accuracy of a p to determine the proport failures the rule identifie ts smoking at follow-up, smoked by week 2? A tine patch users in stu ectively, of those smokin % and 83% had first sm of week 2 (74% across gure). Among placebo idies 1 and 2, respective ing at 6 months, 79% and noked by the end of w s both studies; Figure). ios constitute another ion between early sm rm outcome and reflec n power of a prediction rrect to incorrect deci the prediction rule). V week 2 of treatment marker for outcome a tch users, successful pr atly enhanced at end of t 6.7 and 16.0 for studies ely) and at six months for studies 1 and 2, re le 5). Although smoking e within the first 2 wee of failure to quit, the e that the week 2 rule h the most accurate pr ne least number of mis The power of the week 2 e observed association tcome was .53 in study 2. Similar findings ar

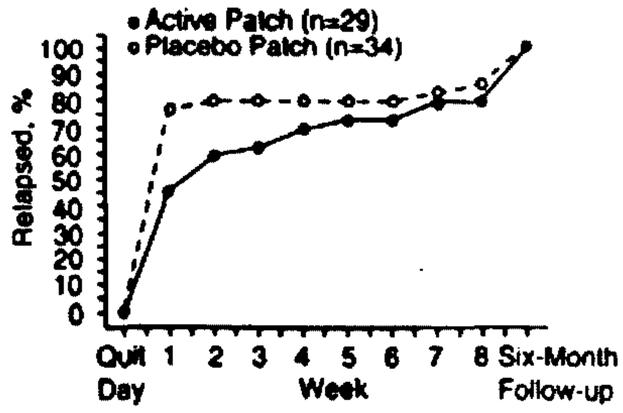
COMMENT

The intent of this research was to identify a simple yet powerful prediction rule that could be used easily in a clinician's office to predict smoking cessation success or failure with or without the nicotine patch. Analyses were based on two separate studies, using two independent samples of smokers, two different adjuvant counseling therapies, and active patch therapy vs placebo patch therapy. In this way these two studies provide an opportunity to test the generalizability of our findings.

The analyses reveal one powerful prediction rule for clinicians: any smoking in the first 2 weeks of treatment predicts both short-term and long-term failure, with week 2 smoking being particularly predictive of outcome (Table 5). Conversely, total abstinence during the first 2 weeks of treatment was consistently correlated with sustained smoking cessation success. By assessing the presence or absence of any smoking during the second week of treatment, clinicians can predict with good accuracy whether the patient will or will not quit smoking. Early detection of high-risk patients may also allow the clinician to modify treatment to increase the likelihood that at-risk patients will succeed.

These analyses also identified a number of factors that did not consistently predict smoking cessation outcome. Specifically, these analyses cast some doubt on the ability of numerous accepted or hypothesized measures of tobacco dependence to predict success or failure consistently for patients using the nicotine patch.[17] Baseline indicators, such as the number of cigarettes smoked per day, Fagerstrom Tolerance Questionnaire score, and years of smoking, were poorly and inconsistently correlated with successful cessation. Biochemical measures also fared poorly as predictors: pretreatment expired CO_a value, pretreatment blood nicotine and cotinine levels, absolute blood nicotine and cotinine levels achieved on the nicotine patch, and the percentage replacement of pretreatment nicotine or cotinine with nicotine patch therapy were poorly and inconsistently correlated with successful smoking cessation. These measures might have shown significant relations with outcome had we had many more subjects in our two studies, but we do not believe that this would change the relative superiority of the week 2 rule to predict outcome.

Our current analyses failed to identify an easy-to-use clinical measure to identify a priori (ie, before treatment begins) smokers who are most likely to succeed or fail with or without the nicotine patch. One caveat to keep in mind is that our results may merely reflect unreliable assessment or the selection of improper measures of



The cumulative proportion of subjects smoking at 6-month follow-up for study 1 (top) and study 2 (bottom), presented as a function of the week at which they smoked their first cigarette (ie, when relapsers started to smoke).

...—Odds Ratios (ORs), 95% Confidence Intervals (CIs), and ϕ Coefficients for Smoking in Weeks 1 and 2 and Abstinence Status at End of Treatment and ...hs in Active Patch Subjects and Placebo Patch Subjects

	Study 1				Study 2			
	End of Treatment		6 Months		End of Treatment		6 Months	
eek	Active Patch (n=44)	Placebo Patch (n=43)	Active Patch (n=44)	Placebo Patch (n=43)	Active Patch (n=57)	Placebo Patch (n=55)	Active Patch (n=57)	Placebo Patch (n=55)
95% CI)	8.4 (2.1-33.5)	11.0 (2.3-51.2)	2.2 (0.6-8.7)	4.1 (0.88-18.9)	8.8 (2.6-29.9)	7.6 (1.8-32.9)	21.2 (2.5-183.7)	1.2 (0.1-12.8)
efficient	.48*	.50*	.18	.28	.48*	.39*	.47*	.02
95% CI)	6.7 (1.7-25.4)	24.9 (4.8-129.0)	4.3 (1.0-18.5)	9.7 (1.7-55.7)	16.0 (4.2-60.7)	23.9 (4.4-130.7)	23.5 (2.7-204.6)	18.9 (1.7-207.8)
efficient	.44*	.66*	.31†	.43*	.59*	.59*	.48*	.41*
95% CI)	7.9 (2.0-31.6)	17.1 (3.0-97.3)	2.8 (0.8-10.4)	4.8 (1.0-22.8)	10.7 (2.8-41.2)	7.9 (1.1-54.9)	19.5 (3.5-109.6)	1.1 (1.0-1.2)
efficient	.46*	.56*	.24	.31†	.49*	.32†	.53*	.09

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dependence. We believe our biochemical confirmation of outcomes, our use of recognized assessment instruments, and the broad array of dependence measures argue against these possibilities. Another caveat is that a restriction of range influenced our results. Our samples consisted of moderately to heavily dependent smokers; a wider inclusive sampling of the dependence continuum may have shown a stronger relationship between outcome and measures of dependence. Moreover, these results may be most relevant to the 24-hour nicotine patches that are used by 90% of the current patch users. Additionally, all our subjects received supportive counseling. Predictive relations might differ for self-quitters vs those in formal treatment programs. Finally, our inability to identify a clinically useful a priori measure may reflect the heterogeneity of smokers in the United States attempting to quit. That is, there may be subtypes of smokers, and no single predictor will perform well across these different subtypes. Finally, as our smokers were enrolled in a university-based clinical research study, these results may not be as powerful in a typical clinic population.

Our results do provide important information for clinicians seeking to aid their patients in quitting smoking. Specifically, the following clinical implications deserve emphasis:

1. Clinicians should stress that total abstinence is central to a successful smoking cessation effort for most smokers.

Optimal smoking cessation counseling should emphasize the importance of early and complete abstinence. Across our two studies, among individuals on the nicotine patch who were abstinent in the second week of treatment, 47% were successfully abstinent at 6 months. In contrast, among individuals who smoked at all in the first 2 weeks of treatment, only 11% were abstinent at 6 months. Most smokers who have previously tried to quit are already aware of the danger of any smoking and provide anecdotal support for this clinical rule. A common report among smokers who had previously relapsed is that they thought they could have a cigarette "now and then" only to quickly relapse to prequit smoking levels.[18] Hall and colleagues[19] have found that those individuals holding a strict abstinence orientation are more likely to achieve long-term success.

2. Clinicians should "front load" smoking cessation counseling and support during the first 2 weeks after quitting.

Among the subset of our patients using the active nicotine patch, 74% of those who ultimately relapsed by 6 months began smoking in the first 2 weeks. Among placebo patch patients who had relapsed by 6 months, 86% began smoking in the first 2 weeks. Clinicians need to provide support and counseling during this critical period of high relapse. For this reason, clinicians should schedule a follow-up visit in person or make contact by telephone[20] during the important first 2 weeks after quitting; review of coping strategies and the importance of total abstinence should be emphasized during this contact.

3. Assess smoking during the second week after the quit attempt to predict smoking cessation outcome.

Smoking during any portion of the treatment period predicted a poor outcome. However, we recommend using any smoking during week 2 as a predictor of outcome because it occurs early in the quit attempt and requires the determination of abstinence for only a brief period of time. Importantly, it is an easy-to-use prediction rule for clinicians: follow-up with the patient in person or by telephone during the second week of a quit attempt—if the patient has smoked at all during this time period, consider an alteration of treatment. More research may result in refinement of this prediction rule, but in our studies, any smoking indicated heightened risk for eventual relapse.

While our results suggest a reliable prediction rule, they do not reveal how treatment should be altered if patients smoke during the first 2 weeks of treatment. Our clinical experience suggests that if a patient is smoking in the second week of treatment, the clinician could consider offering the patient more intensive pharmacotherapy and/or additional adjuvant therapy (perhaps referral to a formal cessation program). However, our clinical experience suggests that these steps should be taken only if the patient is still motivated to stop smoking. If the patient reports feeling discouraged or defeated, treatment may be temporarily withdrawn, allowing the clinician and patient to jointly select a new, future quit date. Obviously, more research is needed to determine appropriate treatment alterations and responses to early failure.

Finally, our results point to two other research needs: first, research aimed at the identification and evaluation of smoker subtypes so that treatment and prediction can be tailored to the individual and second, the feasibility of a graded, stepped-care approach to intervention should be determined.[21] This is the approach used for many medical disorders, such as hypertension or hyperlipidemia, where dose or other dimensions of treatment are increased only when an individual fails to respond to previous treatment. If a similar approach proves effective with smoking cessation, it would serve as a model for clinicians as they combat this devastating chronic disease.[22]

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US DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

JUDITH E. CHAMBERLAIN, AND OTHERS SIMILARLY SITUATED	*	CIVIL ACTION
	*	NO. 96CV2005
VERSUS	*	
THE AMERICAN TOBACCO COMPANY, ET AL.	*	

* * * * * * * * * * * * * * * * * * * *

DECLARATION AND EXPERT'S REPORT OF C. ROBERT CLONINGER, M.D.

1. My name is C. Robert Cloninger, and I am a medical doctor and the Wallace Renard Professor of Psychiatry at Washington University School of Medicine. I am currently licensed to practice medicine in the State of Missouri and I am Board Certified in Psychiatry. I serve as a psychiatric consultant to the American Psychiatric Association, World Health Organization, and National Institutes of Health, and am active in clinical research on the pathogenesis, diagnosis, and treatment of substance dependence. A copy of my curriculum vitae is attached to this report.

2. I understand that the plaintiffs in this proceeding seek to represent a class of persons defined as (a) all nicotine dependent persons who are residents and/or citizens of the State of Ohio who have purchased and/or smoked cigarettes manufactured by the named tobacco companies; (b) the

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estates, representatives, and administrators of these nicotine dependent cigarette smokers; and (c) the spouses, children, relatives and significant others of these nicotine dependent cigarette smokers as their heirs or survivors. Furthermore, the proposed criteria for diagnosis of nicotine dependence include (a) all cigarette smokers who have been diagnosed by a medical practitioner as nicotine-dependent; and/or (b) all regular cigarette smokers who were or have been advised by a medical practitioner that smoking has had or will have adverse health consequences who thereafter do not or have not quit smoking; and/or (c) persons who are or have been nicotine dependent as that phrase is defined under the criteria set forth in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorder, Fourth Edition, 1994 (DSM-IV). In my view, the proposed measures in combination are not reliable diagnostic criteria for nicotine "addiction" or "dependence" and, as proposed for use, do not conform to any diagnostic criteria sanctioned by any official medical or scientific organization. Further in my view, tobacco use is a complex biological, psychological, and social practice, and the assumption that some pharmacological addiction to nicotine explains tobacco use patterns is doubtful. In addition, a determination of who, if anyone, would be in any proposed class of addicted or dependent tobacco users would require

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an indepth evaluation of the facts respecting each individual who claimed to be such a person. This is based on the fact that every individual is unique in terms of genetic composition, education, experiences (adult and child) and level of maturity which define personality. Ignorance of these factors would definitively preclude competent understanding and reliable diagnosis of the individual with a particular behavior pattern.

3. Also, in order to evaluate the claims of the plaintiffs, it is necessary for plaintiffs to define what is meant by the term "addiction." I have examined the statements of David Burns, MD dated February 27, 1997 and of Garland DeNelsky, PhD dated March 1, 1997. The plaintiffs and their experts use the terms "addiction" and "dependence" interchangeably as if these terms both meant that the presence of dependence implied that a person had loss of voluntary control over their decision to smoke cigarettes. Historically, the term addiction has been utilized by scholars, scientists, researchers, clinicians, politicians, bureaucrats and lay people to describe a wide variety of concepts. More recently the term "dependence" has been applied but this too has also been variously used by different people to refer to different concepts. In fact, several authoritative scientific bodies including the World Health Organization (WHO) and the American Psychiatric Association (APA) have

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been struggling with defining these terms. Most recently both the WHO and APA have utilized the term "dependence" to recognize not a simple syndrome but a complex interplay of psychological, social, and biological factors in substance use behavior. In the fourth and latest edition of American Psychiatric Association's Diagnostic and Statistical Manual, substance dependencies are further specified as "with physiological dependence" and "without physiological dependence". Dependencies without physiological dependence correspond to what have traditionally been considered "habits". Dependencies with physiological dependence, manifest by tolerance or withdrawal, may or may not correspond to what has been called an addiction. A substance is traditionally considered to be addictive only if it causes (a) intoxication manifest by impaired cognition and judgment, (b) default of social and occupational responsibilities, (c) physical dependence manifest by a consistently reproducible withdrawal syndrome, and (d) tolerance. According to these criteria, it is doubtful that tobacco or nicotine should be classified as addicting because (a) it does not cause intoxication with impairment of cognition or judgment, (b) even heavy smokers are able to maintain their social and occupational responsibilities without difficulty, (c) abstinence produces either no withdrawal symptoms or at most mild anxiety symptoms, and

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(d) individuals maintain enjoyment of smoking the same number of cigarettes for many years. In short, the nature and definition of possible nicotine addiction is not settled in the scientific community. The proposed criteria for nicotine dependence do not provide a reliable means to distinguish individuals who are responsible for their decision to smoke from others.

4. The evolution of the nicotine dependence criteria in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) is illustrative of the controversy as outlined above but has been even more problematic because the properties of nicotine are not as clearly defined as those of narcotics, alcohol, or cocaine. The first time a diagnosis for "tobacco dependence" appeared in the Diagnostic and Statistical Manual (DSM) was in the third edition (DSM-III) which was published in 1980. The earlier editions of DSM included diagnoses for other substance use dependencies but no such diagnosis for tobacco use. The inclusion of a diagnosis for "tobacco dependence" and later (1987) for "nicotine dependence" has been the subject of much controversy within the profession. The criteria for making the diagnosis changed from the original criteria in DSM-III when a revision was published in 1987, that being DSM-III-R, and changed still again with the recent publication this year of DSM-IV. Throughout this period,

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the changes in diagnostic criteria reflected the existence of widespread disagreement within the substance abuse community over the standards to define a dependence to tobacco. Moreover, the changes in diagnostic criteria have reflected tension over whether dependence is physical in nature or solely psychological in nature. In 1988, the Surgeon General chose to use the term addiction in his public health statements about tobacco and nicotine, even though many scientists and medical practitioners regard that term as overly simplistic, pejorative, and therapeutically counterproductive in clinical practice. The oversimplified model that tobacco use may sometimes lead to nicotine dependence suggests that desire to use tobacco is motivated solely by the physical need to maintain nicotine levels and that smokers are unable to control their desire for nicotine. This model is inadequate for clinical practice or public health policy because the desire to smoke is a learned habit that is determined by many individual personal and social factors and is not attributable simply to nicotine levels. For example, nicotine levels do not predict success in stopping smoking, and nicotine replacement therapy does not reduce the desire to smoke. Self-directed regulation of lifestyle goals is the major determinant of success in stopping smoking. Accordingly, it is counterproductive to give people an excuse for their

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decision not to stop smoking by saying that they are addicted to nicotine when the major determinant of successful cessation is the personal decision and commitment not to smoke.

5. This lack of consensus on what defines a dependence with respect to tobacco usage underscores the fact which is of paramount importance in this case, i.e., that people smoke for very different reasons, they smoke in very different patterns, their motives to quit are very different and their efforts to quit are very different. There is simply no universal set of criteria which accurately classifies patterns of smoking behavior for each and every individual smoker.

Let us consider each of the three measures proposed by the plaintiffs. The first proposed test, diagnosis of nicotine dependence by a medical practitioner, would be based on information of variable content and uncertain validity since different practitioners have different concepts for diagnosis and patients often provide inaccurate and misleading information about the extent of their desire to smoke or not to smoke. For example, current DSM-IV criteria for nicotine dependence require a maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three or more of the following seven

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features, occurring during the same 12-month period: (1) tolerance, (2) withdrawal, (3) taking the substance in larger amounts or over a longer period than was intended, (4) unsuccessful efforts to cut down or control use, (5) a great deal of time expended to obtain and use the substance (e.g. chain-smoking), (6) giving up social, occupational, or recreational activities to smoke, and (7) continued use despite adverse medical consequences. It is simply not possible to make a diagnosis of nicotine dependence with a reasonable degree of medical certainty unless a physician has extensive and reliable facts in evidence about the person's overall lifestyle, patterns of impulse control or lack thereof, peer pressures, personal enjoyment of smoking, and the strength of the desire to stop smoking. Unfortunately, some medical practitioners may make the diagnosis of nicotine dependence if a patient claims to have tried to stop smoking, even if they have never gone more than a day without doing so. Leaving the basis for diagnosis to individual practitioner judgment without allowance for any test of the accuracy of the basis for the diagnosis or the criteria that were applied does not satisfy a test of common sense.

The second proposed measure, continuing to smoke despite medical warning about possible adverse health

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consequences, would admit someone to the class who satisfies none of the set of seven criteria described earlier, instead of requiring at least three as DSM-IV does. For example, the proposed measure could be applied to any smoker, regardless of their frequency and pattern of smoking, and even if they have no adverse health consequences if a physician warns them to stop because they might develop health consequences in the future. Such a criterion does not allow consideration of the personal and social factors motivating an individual's choice to continue smoking. For example, like other risk-benefit decisions, such as the choice to to gamble in a casino, to drive on busy highways, to eat beef, sweets, or fried foods regularly, a person may simply like to smoke and choose to do so to satisfy their desires, making a calculated decision that immediate satisfaction outweighs immediate and future risks. It is not reasonable to expect compensation if one makes such a choice and is later dissatisfied with the consequences, any more than it would be sensible to compensate gamblers when they lose.

As another example of the need to examine specific facts about each case, does the individual have a personality disorder with severe immaturity and little impulse-control in any aspect of their life, or does the person

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have a specific inability to stop smoking while having good impulse control otherwise? Individuals who participate in smoking cessation programs vary widely in the extent to which they personally want to stop smoking, yet this would not be taken into account. Likewise, the response to advice to stop smoking varies widely, for example, depending on the severity of the medical problem, the relationship of the doctor to the patient, the way the information is communicated (e.g. emphasis and empathy), and the personality and mental status of the patient.

The third test, a diagnosis of nicotine dependence as defined in DSM-IV, does not require evidence of physiological dependence, inability of the smoker to regulate their desire to smoke, or impaired judgment and cognition from intoxication. In summary, no one test, including any of the three proposed by the plaintiffs, is an adequate and reliable basis to decide the responsibility of the plaintiffs for their voluntary choices and behavior. Detailed psychiatric assessment of each individual is required before a diagnosis of nicotine dependence could be justified with a reasonable degree of medical certainty.

6. Whatever definition of addiction or dependency is used, the application of criteria to define such addiction or

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dependency necessarily requires a detailed examination of individual facts. For example, the recent DSM-IV instructs that a diagnosis of any substance dependence requires that there be "clinically significant impairment or distress" (page 181). It requires a clinician to obtain "a detailed history from the individual and whenever possible, from additional sources of information (e.g., medical records, a spouse, a relative, or a friend). In addition, physical examination findings and laboratory test results can be helpful" (page 185).

7. Moreover, the application of any of the criteria that have been advanced for tobacco dependence does not predict whether a person can in fact quit smoking. Smokers quit smoking all the time, and usually do not require any help to do so once they have made up their mind to quit. It is estimated that over 45 million smokers in the United States have quit smoking since publication of the Surgeon General's Report in 1964. It is well accepted that the smokers who have been diagnosed as dependent under DSM can quit smoking if sufficiently motivated.

C Robert Cloninger — 4/18/97

C. Robert Cloninger, MD — Date

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C. Robe[redacted]r, M.D.

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Education:

University of Texas, Austin, Texas, 1962-1966, B.A. with high honors and special honors in Plan II (Philosophy, Psychology, and Anthropology).

Washington University School of Medicine, St. Louis, MO 1966-1970, M.D.

Epidemiology Field Research Trainee, California State Department of Public Health, Berkeley, California, July 1967-September 1967.

Student Research Fellow (with S.B. Guze), Washington University School of Medicine, St. Louis, Missouri, June 1969-October 1969.

Assistant Resident-Assistant and Trainee (NIMH) in Psychiatry Washington University School of Medicine, St. Louis, Missouri, July 1970-June 1973.

Research Scientist Development Awardee (NIMH) in Quantitative Genetics, July 1975-1985.

Visiting Investigator, Population Genetics Laboratory, University of Hawaii at Manoa, July 1978-June 1979.

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Academic Positions/Employment:

Instructor in Psychiatry, Washington University School of Medicine, St. Louis, Missouri, July 1973-June 1974

Assistant Professor of Psychiatry, Washington University School of Medicine, St. Louis, Missouri, July 1974-June 1978.

Associate Professor of Psychiatry, Washington University School of Medicine, St. Louis, Missouri, July 1978-June 1981.

Associate Professor of Genetics, Washington University School of Medicine, St. Louis, Missouri, July 1979-June 1981

Visiting Professor of Psychiatry and Genetics, University of Umea School of Medicine, Umea, Sweden, May to June, 1980.

Professor of Psychiatry and Genetics, Washington University School of Medicine, July 1981-Present.

Head, Department of Psychiatry, Washington University School of Medicine, July 1989-March 1994

Professor of Psychology, Washington University, July 1989-present.

Wallace Renard Professor of Psychiatry, Washington University, July 1991-present

Director, Center for Psychobiology of Personality, March 1994-present

Hospital Appointments:

Barnes and Allied Hospitals, St. Louis, MO
- Assistant Psychiatrist, July 1973-June 1980
- Associate Psychiatrist, July 1980-June 1981
- Psychiatrist, July 1981-present
- Psychiatrist-in-chief July 1989-

Children's Hospital of St. Louis
- Psychiatrist-in-chief, July 1989-June 1991

Malcolm Bliss Mental Health Center, St. Louis, MO
- Consulting Psychiatrist, July 1973-Present

Jewish Hospital of St. Louis, MO
- Associate Psychiatrist, July 1976-June 1980
- Psychiatrist, July 1980-Present
- Director of Outpatient Psychiatry, July 1976-June 1989

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Other University Appointments and Committees:

Steering Committee Member, McDonnell Center for Higher Brain Function, 1989 - 1993

Steering Committee Member, WUMS Howard Hughes Program, 1990 - 1993

Chair, Division of Biostatistics Advisory Committee, 1989 - 1993

Member, Health Care Administration Advisory Committee, 1989 - 1993

Member, Occupational Therapy Program Advisory Committee, 1990 - 1993

Medical Licensure and Board Certifications:

State Board of the Healing Arts of Missouri, Physicians and Surgeons #32703, issued June 20, 1970

Missouri Controlled Substance Registration #210508

Bureau of Narcotic and Dangerous Drugs #AC4359419

Diplomate, American Board of Psychiatry and Neurology, 1975

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Honors and Awards:

Institute of Medicine, National Academy of Sciences, USA,
elected active member, May 1989 - present

Phi Beta Kappa - 1965

Phi Beta Sigma - 1963

Alpha Epsilon Delta - 1965

Sandoz Award for Research in Psychiatry, Washington University School of Medicine (1970)

Research Scientist Development Awards:

Type 1 (1975-1980) MH-0048. The transmission and prognosis of psychiatric disorders (Quantitative Genetics and Environmental Genetic Interaction)

Type 2 (1980-1985) Genetic epidemiology of psychiatric disorders

Research Scientist Award (MH-00048)

Genetic Epidemiology of Psychiatric Disorders (1985-1989) (Resigned to accept chairmanship)

Endowed Visiting Professorships

Milton and Harriet Parker Memorial Lecturer, Ohio State University, Department of Psychiatry, September 1983 and December 1985

John Nielson Distinguished Lecturer, University of Utah, Department of Psychiatry, April 1988

Stewart Wolf Distinguished Lecturer, University of Oklahoma, Department of Medicine, May 1988

James Brady Lecturer, University of Colorado, 1989

Frank H. Luton Lecturer, Vanderbilt University, 1989

William D. Stubenbord Visiting Professor,
Cornell University Medical College and the Louis Calder Foundation, September, 1991

Other Distinguished Lectureships

Sigma Xi Lecturer on Natural Sciences, University of North Carolina, October 1987

NIH Centennial Lecturer, Washington, DC, September 1987

Plenary Lecturer, Research Society on Alcoholism, June 1988

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Pfizer Visiting Professor, Columbia University and New York State Psychiatric Institute, October 1991

Gudbrandsdalen Medalist & Lecturer, Norwegian Medical Research Council, Lillehammer, Norway, 1992

Keynote Speaker, Australian-New Zealand Psychiatric Association Annual Meeting, Christchurch, New Zealand, 1993

Lederle Visiting Professor, Hospital de la Salpetriere, Paris, France, December, 1993

Honorary Doctor of Medicine (M.D. honoris causa), University of Umea (Sweden), October 1983 for distinguished contributions to genetic epidemiology of psychiatric disorders

Strecker Award (The 25th Annual Institute of Pennsylvania Hospital Award in Memory of Edward A. Strecker, M.D.), 1988 for significant contributions to psychiatric patient care and treatment by studies of the assessment and inheritance of personality and psychopathology

Edgehill Newport Scientific Recognition Award, May 1990, in recognition of outstanding contributions to the treatment of chemically dependent persons through basic research

Mortimer Goodman Memorial Award, The Alliance for the Mentally Ill of Metro St. Louis, in recognition of outstanding service as a physician, researcher, administrator, public servant and friend, May 1992

James B. Isaacson Memorial Award, June 1992, International Society for Biomedical Research on Alcoholism and National Foundation for Prevention of Chemical Dependency Disease, for excellence in scientific research into the causes of chemical dependency diseases

Samuel Hamilton Award, March 1993, American Psychopathological Association, for contributions to understanding personality and psychopathology

Adolf Meyer Award, May 1993, American Psychiatric Association, for outstanding contributions to the science and practice of psychiatry

Editorial Responsibilities:

Editor, Behavior Genetics (1980-1986)
Associate Editor,
American Journal of Human Genetics (1980- 1983)
Journal of Clinical Psychiatry (1981-1987)

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Genetic Epidemiology (1983-1991)
Human Heredity (1989-Present)
Field Editor, Neuropsychiatric Genetics, American Journal Medical Genetics (1992 -)
Editorial Boards,
Archives of General Psychiatry (1987-)
Neuropsychopharmacology (1991-)
Comprehensive Psychiatry (1992-)
Journal of Psychiatric Research (1993-)

Professional Societies and Organizations:

Advances in Neuropyschiatry and Psychopharmacology
Editorial Board - Raven Press (1991-1993)

American Association for the Advancement of Science, Member (1976-Present)

Representative of the Behavior Genetics Association Section Committee for Medical Sciences (Section N) (1986-1989)

American College of Neuropsychopharmacology, Member (1987-)
Committee on Issues of Public Concern (1988-)

American Medical Association, Member (1982-Present)

American Psychiatric Association, Member (1975-1979)
Fellow (1980-Present)

American Psychopathological Association, Fellow (1976-Present)
Membership Chairman (1978-1984)
Treasurer (1984-1990)
Vice-President (1990-1991)
President-Elect (1991-1992)
President (1992-1993)

American Society of Human Genetics, Member (1976-Present)

Behavior Genetics Association, Member (1976-Present)
BGA Representative to AAAS Section Committee for Medical Sciences
Chairman, Publications Committee (1986-1989)

Center for Advanced Study in the Behavioral Sciences,
Academic Psychiatry Consortium
(1990-1993, 1993-1996)

Eastern Missouri Psychiatric Society, Member (1973-Present)

International Society for Study of Personality Disorders,
Board of Directors - (1991 -)
President, American Region - (1993 -)

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Psychiatric Research Society, Member (1977-Present)

Research Society on Alcoholism (1981-Present)
Committee on Research Development (1984-Present)
Member, Board of Directors (1987-1990)
Committee on Issues of Public Concern (1989-91)

Society of Biological Psychiatry, Member (1977-Present)

Consulting Relationships and Board Memberships:

Consultant, American Psychiatric Association
Task Force on Nomenclature (Diagnostic and Statistical Manual - III), 1978-1980
Task Force to Evaluate DSM-III, 1983-
Committee to Revise DSM-III, 1984-1987
Task Force on DSM-IV, 1988-

Psychiatric Consultant and Member of Professional Advisory Council, Suicide Prevention Service of Madison - St. Clair Counties (1971-1993)

Psychiatric Consultant, 3rd Judicial Circuit of Illinois (1973-1974)

Special Consultant and Site Visitor, NIMH Clinical Program Projects and Clinical Projects Review Committees (1977-1980)

NIMH Psychopathology and Clinical Biology Research Review Committee:
Consultant and Committee Member (1980-Present)
Chairman, Psychopathology Subcommittee (June 1981-1983)
Chairman (June 1983-July 1984)

Scientific Advisor and Consultant, NIMH Affective and Anxiety Disorders Research Branch (1986-1989)

Scientific Advisory Board
Children of Alcoholics Foundation (1989 - present)

Consultant to Director, NIAAA (1984-Present)
Board of Scientific Counselors (1988-)

Consultant, World Health Organization (WHO)/ADAMHA Advisory Group on Diagnosis and Classification of Mental Disorders, and Alcohol - and Drug-Related Problems (1981-1985)
Consultant Psychiatrist (1993-present)

Member, Research Advisory Council, Texas Department of Mental Health and Mental Retardation (1983-1985)

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Extramural Scientific Advisor and Consultant
Chicago Medical School, Department of Psychiatry (1977)
New York University Medical School, Psychiatry (1980-82)
University of Minnesota, Dight Laboratories, Genetics (1985-88)
University of Connecticut, Alcoholism Research Center (1986-91)
University of Pennsylvania, Clinical Research Center (1987-present)
University of Colorado, Alcohol Research Center (1991-)

University of Oklahoma,
Alcoholism Research Center (1987-92)

Honorary Member - IBC Advisory Council, 1989

Scientific Advisory Board - Oklahoma Center of Molecular Medicine, 1990

Missouri Mental Health Commission - (9/26/90 - 6/28/94)

Pfizer Visting Professorship in Psychiatry Academic Advisory Committee, 1993

Research Support:
Governmental:

NIMH, MH31302, Epidemiological Genetics and Family Study, C.R. Cloninger, M.D., P.I.; 08/01/86 - 07/31/96

NIAAA, AA07982, Prediction of Alcohol Abuse in Swedish Adoptees, C.R. Cloninger, M.D. P.I.; 07/01/88 - 06/30/95

NIAAA, AA08028, Molecular Genetic Studies of Alcoholic Subtypes, C.R. Cloninger, M.D., P.I.; 12/01/88 - 11/30/95

NIMH, MH46276, Diagnostic Center for Linkage Studies of Schizophrenia, C.R. Cloninger, M.D., P.I.; 09/30/89 - 08/31/94

NIAAA, AA08401, Collaborative Studies on the Genetics of Alcoholism, Coordinating Center, Theodore Reich, M.D., P.I.; 10/01/89 - 09/30/94

NIMH, MH46280, Diagnostic Center for Linkage Studies of Bipolar Disorder, Theodore Reich, M.D., P.I.; 09/30/89 - 08/31/94

MH14677, Research Training in Clinical Sciences, C.R. Cloninger, M.D., P.I.; 07/01/92 - 06/30/97 (transferred to T. Reich, 7/1/93)

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Teaching Titles and Responsibilities:

Coursemaster, Introduction to Clinical Psychiatry - Washington University School of Medicine II (1976-1989)

Committee on Academic Review and Promotion (1976-1989)

Lecturer, Medical Genetics, Washington University School of Medicine (1980-Present)

Clinical Sciences Postdoctoral Training Program
Preceptor (1975-Present)
Psychiatric Genetics Director (1980-Present)
Overall Program Director (1985-1993)

RESEARCH TRAINEES
Current Trainees

Betty Lobos, B.S., Predoctoral Graduate Student (1985-1993)
Training: Quantitative and molecular genetics.
Dissertation Topic: Genetics of Nicotine Acetylcholine Receptor.

Past Trainees

Sean Yutzy, M.D., Postdoctoral Fellow, (1990-1992)
Training: Nosology of somatoform and personality disorders
Currently: Assistant Professor of Psychiatry, Washington University School of Medicine

Dragan M. Svrakic, M.D., Ph.D., Fulbright Scholar from University of Belgrade, Yugoslavia (Sept 88-Aug 89)
Training: Collaboration on Cross-cultural studies of personality assessment and structure.
Currently, Assistant Professor of Psychiatry, Washington University School of Medicine

Stephen Dinwiddie, M.D., Postdoctoral Fellow (1987-1990)
Training: Clinical and genetic methods for studying neuroadaptive processes in substance abusers.
Currently: Assistant Professor of Psychiatry, Washington University School of Medicine

Ronald Martin, M.D., Psychiatry Resident, 1975-1977
Training: Supervised his follow-up of female felons I had previously studied; trained in conduct and analysis of longitudinal clinical studies
Currently: Professor & Chairman of Psychiatry, University of Kansas at Wichita.

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Collins E. Lewis, M.D., M.P.H., Psychiatry Resident, 1975-1977
Training: Supervised clinical and family study of alcoholics; trained in epidemiological methods and family studies.
Currently: Associate Professor of Psychiatry, Washington University.

William Coryell, M.D., Psychiatry Resident, 1977
Training: Supervised his participation in a reliability study of a new structured interview; trained in methods for conducting and interpreting reliability studies.
Currently: Professor of Psychiatry, University of Iowa.

John P. Rice, Ph.D., Postdoctoral Fellow, 1975-1977
Training: Directed reading about psychiatric genetics and genetic epidemiology; we jointly worked on extending methods for cultural inheritance and segregation analysis.
Currently: Professor of Psychiatry & Biostatistics, Washington University.

Andrew Scallet, Ph.D., Predoctoral Psychology Student, 1975-1976
Training: Supervised research on assessment and double-blind treatment studies of outpatients.
Currently: Research Psychologist, National Center for Toxicological Research, Jefferson, Arkansas

Lenore Teter, M.D., Psychiatry Resident, 1980
Training: Supervised research on psychiatric social adjustment of recent Russian immigrants.
Currently: Instructor in Psychiatry, Washington University, then private practice

Robert Desalle, B.S., Predoctoral Genetics Fellow, 1979
Training: Method of path analysis in studying inheritance of complex phenotype systems.
Currently: Completed dissertation in Genetics, Washington University.
Currently: Department of Biology, Yale University

Peter McGuffin, M.D., Postdoctoral Fellow, 1980-1981
Training: Advanced methods of genetic epidemiology including segregation, path, admixture, and linkage analysis.
Currently: Professor & Chairman of Psychiatry, Cardiff, England

Paul Van Eerdewegh, Ph.D., Predoctoral Fellow, 1980-1982
Training: Studies of statistical properties of copaths and selection in multivariate systems relevant in quantitative genetics.
Currently: Assistant Professor in Psychiatry in Genetic Epidemiology, Washington University.

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Dennis O'Rourke, Ph.D., Postdoctoral Fellow, 1980-1983
Training: Advanced methods of genetic epidemiology including segregation, path, and linkage analysis.
Currently: Professor of Anthropology, University of Utah.

Anne-Liss von Knorring, M.D., Postdoctoral Fellow, 1982-1983.
Training: Methods of genetic epidemiology relevant to adoption studies.
Currently: Professor of Child Psychiatry, University of Uppsala, Sweden.

Soren Sigvardsson, D. Med. Sci., Predoctoral Fellow, 1981
Postdoctoral Fellow, 1983
Training: Methods of genetic epidemiology and multivariate analysis relevant to adoption studies; longitudinal and cross-fostering studies of adoptees with relevance to child psychiatry.
Currently: Associate Professor of Child Psychiatry, Umea University.

Nancy J. Cox, Ph.D., Postdoctoral Fellow, 1982
Training: Advanced methods of genetic epidemiology for studying psychiatric disorders.
Currently: Assistant Professor, University of Chicago.

Eric Devor, Ph.D., Postdoctoral Fellow, 1982
Training: Advanced methods of genetic epidemiology in anthropology; population structure.
Currently: Assistant Professor of Psychiatry, University of Iowa, Iowa City

Mark Zoccolillo, M.D., Psychiatry Resident, 1983
Training: Supervised design and analysis of clinical and social comparison of matched groups of outpatients with somatoform and affective disorders; study of parenting and home environmental influences on children of outpatients.
Currently: Assistant Professor of Psychiatry, Texas Tech

Edward Lauterbach, M.D., Psychiatry Resident, 1984
Training: Design and analysis of psychiatric follow-up studies.
Currently: Associate Professor of Psychiatry, (Tenure)
Mercer University School of Medicine, Macon, Georgia

Kara Forest, B.A., Biology Honors Student, 1986
Training: Etiology of anxiety states.
Currently: Medical school

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Wolfgang Baier, M.D., FRG Postdoctoral Fellow, 1987
Training: Genetic epidemiology of generalized minor seizures (collaborative project with Professor Doose at University of Kiel, FRG)
Currently: Child Neurologist, University of Kiel

David Craufurd, M.D., Wellcome Trust Fellow, 1987.
Training: Psychiatric Genetics.
Currently: Research Psychiatrist, St. Mary's Hospital, University of Manchester, England.

Sheila B. Gilligan, B.S., Predoctoral Graduate Student (1983-1988)
Training: Quantitative genetics of common diseases.
Dissertation Topic: Genetic and Phenotypic Heterogeneity in Alcoholism (scheduled to complete Spring, 1988).
Currently: Postdoctoral Fellow in Human Genetics, Medical College of Virginia (Dr. Andrew Heath), then Peace Corps in Africa.

Vicky Ryan, Undergraduate biology honors student (1987-1988)
Training: Techniques in family studies of alcoholism.
Currently: Medical School, University of Missouri

David L. Garver, M.D., Sabbatical Leave from University of Cincinnati, Depts. of Psychiatry and Pharmacology (Sept 88-Aug 89)
Training: Psychiatric genetics including clinical and molecular aspects.
Currently: Professor of Psychiatry, Southwestern Medical School, Dallas, Texas

Harald and Gabrielle Aschauer, M.D., Medical Research Council of Austria Fellows
Training: Neuropsychopharmacologist/psychiatrist coming for training in genetics of schizophrenia (Sept 87-March 1989).
Currently: Assistant Professors in Vienna

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Bibliography

Articles - 1970

1. Cloninger CR and Guze SB: Psychiatric Illness and Female Criminality: The Role of Sociopathy and Hysteria in the Antisocial Women. Amer. J. Psychiat., 127(3):303-311, 1970.

2. Cloninger CR and Guze SB: Female Criminals: Their Personal, Familial, and Social Backgrounds (The Relations of These to the Diagnoses of Sociopathy and Hysteria). Arch. Gen. Psychiat., 23:554-558, 1970.

Articles - 1973

3. Cloninger CR and Guze SB: Psychiatric Illness in the Families of Female Criminals: A Study of 288 First-Degree Relatives. Brit. J. Psychiat., 122:697-703, 1973.

4. Cloninger CR and Guze SB: Psychiatric Disorders and Criminal Recidivism: A Follow-up Study of Female Criminals. Arch. Gen. Psychiat., 29:266-269, 1973.

Articles - 1974

5. Hearst ED, Cloninger CR, Crews EL, and Cadoret RJ: Electrosleep Therapy: A Double Blind Trial. Arch. Gen. Psychiat., 30:463-466, 1974.

6. Cloninger CR: Group Rape: A Commentary. Med. Aspects of Human Sexuality, 8:81, 1974.

7. Cloninger CR, Packman PM, Cicero TJ, Boshans RL, and Robins E: Morphine Dependence and Enzyme Activity in the Hypothamus. Biochem. Pharmacol. 23:983-988, 1974.

Articles - 1975

8. Cloninger CR and Guze SB: Hysteria and Parental Psychiatric Illness. Presented at the Annual Meeting of APA, 1973. Psychol. Med., 5:27-31, 1975.

9. Reich T, Cloninger CR, and Guze SB: The Multifactorial Model of Disease Transmission: I. Description of the Model and its Use in Psychiatry. Brit. J. Psychiatry, 127:1-10, 1975. (Science Citation Index Citation Classic)

10. Cloninger CR, Reich T, and Guze SB: The Multifactorial Model of Disease Transmission: II. Sex Differences in the Familial Transmission of Sociopathy (Antisocial Personality). Brit. J. Psychiatry, 127:11-22, 1975.

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11. Cloninger CR, Reich T, and Guze SB: The Multifactorial Model of Disease Transmission: III. Familial Relationship Between Sociopathy and Hysteria (Briquet's Syndrome). Brit. J. Psychiatry, 127:23-32, 1975.

12. Cloninger CR: Recognizing and Treating Sociopathy. Medical World News, 16(23):12-18, 1975.

13. Cloninger CR, Reich T and Guze SB: Genetic-Environmental Interactions and Antisocial Behavior. In Psychopathic Behavior: Approaches to Research, (Eds. RD Hare and D Schallings). Proceedings of the NATO Advanced Study Institute on Psychopathic Behavior, Les Arcs, France. September 5-12, 1975. Chichester: John Wiley and Sons, 1978, pages 225-238.

14. Cloninger CR: The Link Between Hysteria and Sociopathy. Chapter 11 in Psychiatric Diagnosis: Exploration of Biological Predictors. Predictors in Psychiatric Diagnosis, Memphis, Tennessee, December 7-9, 1975. (Eds. HS Akiskal and WL Webb). New York: Spectrum, Inc. 1978, pages 189-218.

Articles - 1976

15. Scallet A, Cloninger CR, and Othmer E: The Management of Chronic Hysteria: A Review and Double Blind Trial of Electrosleep and Other Relaxation Methods. Dis. Nerv. System, 37(6):347-353, 1976.

16. Woodruff RA, Clayton P, Cloninger CR, and Guze, SB: A Brief Method of Screening for Alcoholism. Dis. Nerv. System, 37(8):434-435, 1976.

Articles - 1977

17. Hill S, Cloninger CR, and Ayre F: Independent Familial Transmission of Alcoholism and Opiate Abuse. Alcoholism: Clinical and Experimental Research, 1(4):335-342, 1977.

18. Guze SB, Akiskal HS, Cadoret R, Cloninger CR, Matthysse S, and Rosenthal D: Family and Genetic History as Diagnostic Predictors. Chapter 12 in Psychiatric Diagnosis: Exploration of Biological Predictors, op. cit., pages 219-233.

19. Liskow BI, Clayton P, Woodruff R, Guze SB, and Cloninger CR: Briquet's Syndrome, Hysterical Personality, and the MMPI. Amer. J. Psychiat., 134(10):1137-1139, 1977.

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Articles - 1978

20. Cloninger CR, Christiansen KO, Reich T, and Gottesman II: Implications of Sex Differences in the Prevalence of Antisocial Personality, Alcholism, and Criminality for Models of Familial Transmission. Arch. Gen. Psychiat., 35:941-951, 1978.

21. Martin RL, Cloninger CR, and Guze SB: Female Criminality and the Prediction of Recidivism: A Prospective Six Year Follow-up. Arch. Gen. Psychiat., 35:207-214, 1978.

22. Coryell W, Cloninger CR, and Reich T: Clinical Assessment: Use of Non-Physician Interviewers. J. Nerv. Ment. Dis., 166(8):599-606, 1978.

23. Powell C, Miller JP, and Cloninger CR: The Use of SAS for the Analysis of Family Studies. In Strand, RH (Ed.), Proceedings of the Third Annual Conference on the SAS User's Group International. SAS Institute, Inc., Raleigh, North Carolina, 1978, pp. 189-194.

24. Reich T, Cloninger CR, Lewis CE, and Rice J: Familial Structures in Models of Cultural Inheritance. In NE Morton and CS Chung (Eds.) Genetic Epidemiology. Academic Press, 1978, pp. 183-191.

25. Cloninger CR, Matthysse S, Anderson VE, and Morton NE: Panel Discussion: Resolution of Etiologic Heterogeneity in the Psychoses. In NE Morton and CS Chung (Eds.), Genetic Epidemiology. Academic Press, 1978, pp. 329-330.

26. Rice J, Cloninger CR, and Reich T: Multifactorial Inheritance with Cultural Transmission and Assortative Mating. I. Description and Basic Properties of the Unitary Models. Am. J. Hum. Genet., 30:618-643, 1978.

27. Cloninger CR: Antisocial Personality. Hospital Practice, 13(8):97-112, 1978. Reprinted in Guggenheim F, Nadelson CC (Eds.), Handbook of Major Psychiatric Disorders: Overviews and Selected Readings. Elsevier North Holland, pp. 169-178, 1982.

Articles - 1979

28. Cloninger CR, Miller JP, Wette R, Martin RL, Guze SB: The Evaluation of Diagnostic Concordance in Follow-up Studies: I. A General Model of Causal Analysis and a Methodological Critique. J. Psychiat. Research, 15:85-106, 1979.

29. Martin RL, Cloninger CR, Guze SB: The Evaluation of Diagnostic Concordance in Follow-up Studies: II. A Blind Prospective Follow-up of Female Criminals. J. Psychiat. Research, 15:107-125, 1979.

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30. Cloninger CR, Reich T, Wetzel R: Alcoholism and the Affective Disorders: Familial Association and Genetic Models. In: Alcoholism and the Affective Disorders (eds. D Goodwin and C Erickson). New York: Spectrum Press, pages 57-82, 1979.

31. Reich T, Rice J, Cloninger CR, Wette R, James J: The Use of Multiple Thresholds and Segregation Analysis in Analyzing the Phenotypic Heterogeneity of Multifactorial Traits. Annals of Human Genetics, London, 42(3): 371-390, 1979.

32. Cloninger CR, Rice J, Reich T: Multifactorial Inheritance with Cultural Transmission and Assortative Mating. II. A General Model of Combined Polygenic and Cultural Inheritance. Am. J. Hum. Genet., 31:176-198, 1979.

33. Cloninger CR, Rice J, Reich T: Multifactorial Inheritance with Cultural Transmission and Assortative Mating. III. Family Structure and the Analysis of Separation Experiments. Am. J. Hum. Genet, 31:366-388, 1979.

34. Rice J, Reich T, Cloninger CR, Wette R: An Approximation to the Probabilities of the Multivariate Normal Distribution: Its Application to the Multifactorial Model of Qualitative Traits. Biometrics, 35:451-459, 1979.

35. Rao DC, Morton NE, Cloninger CR: Path Analysis Under Generalized Assortative Mating. I. Theory. Genetical Research, Cambridge: 33:175-188, 1979.

Articles - 1980

36. Reich T, Rice J, Cloninger CR, Lewis C: The Contribution of Affected Parents to the Pool of Affected Individuals: Path Analysis of the Segregation Distribution for Alcoholism. In: The Social Consequences of Psychiatric Illness, LN Robins, P Clayton, J Wing, (Eds.) Brunner/Mazel, pp. 91-113, 1980.

37. Rice J, Cloninger CR, Reich T: The Analysis of Behavioral Traits in the Presence of Cultural Transmission and Assortative Mating. Application to IQ and SES. Behavior Genetics, 10:73-92, 1980.

38. Wetzel RD, Cloninger CR, Hong B, Reich T: Personality as a Subclinical Expression of Affective Disorder. Comprehensive Psychiatry. 21:197-205, 1980.

39. Reich T, Cloninger CR, Lewis C, Rice J: Some Recent Findings in the Study of Genotype-environment Interactions in Alcoholism. Proceedings of the University of Connecticut - NIAAA Conference on "Evaluation of the Alcoholic: Implications for Research, Theory, and Treatment", NIAAA Research Monograph Series, pp. 145-165, 1980.

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40. Reich T, Suarez B, Rice J, Cloninger CR: Current Directions in Genetic Epidemiology. In: Current Developments in Anthropological Genetics, Vol. I (J Mielke and M Crawford, eds.), Plenum Press, New York, pp 299-324, 1980.

41. Cloninger CR, Lewis C, Rice J, Reich T: Strategies for the Resolution of Biological and Cultural Inheritance. In: Genetic research Strategies for Psychobiology and Psychiatry. (ES Gershon, S Matthysse, XO Breakefield, RD Ciaranello, editors). Boxwood Press, Pacific Grove, California, pages 319-332, 1980.

42. Reich T, Rice J, Cloninger CR: The Detection of a Major Locus in the Presence of Multifactorial Variation. In: Genetic Research Strategies for Psychobiology and Psychiatry, op. cit, pp. 353-368, 1980.

43. Rice J, Cloninger CR, Reich T: General Causal Models for Sex Differences in the Familial Transmission of Multifactorial Traits: An Application to Human Spatial Visualizing Ability. Social Biology, 27:36-47, 1980.

44. Cloninger CR: Interpretation of Intrinsic and Extrinsic Structural Relations by Path Analysis: Theory and Applications to Assortative Mating. Genetical Research, Cambridge, 36:122-145, 1980.

Articles - 1981

45. Cloninger R, Martin RL, Guze SB, Clayton P: A Blind Follow-up and Family Study of Anxiety Neurosis: Preliminary Analysis of the St. Louis 500. In: Anxiety: New Research and Changing Concepts, edited by DF Klein and J Rabkin. New York: Raven Press, pages 137-150, 1981.

46. Rice J, Miller JP, Cloninger CR: Path Analytic Models in Human Quantitative Genetics. In Proceedings of the Sixth Annual Conference of the SAS User's Group International. Institute, Inc., Raleigh, North Carolina, pp. 110-115, 1981.

47. Rice J, Reich T, Cloninger CR: Models for the Familial Transmission of Alcoholism: Path Analysis and Multifactorial Segregation Analysis. Psychopharmacology Bulletin, 17:40-42, 1981.

48. Cloninger CR, Bohman M, Sigvardsson S: Inheritance of Alcohol Abuse: Cross-fostering Analysis of Adopted Men. Arch. Gen. Psychiatry, 38:861-868, 1981.
(Science Citation Index Citation Classic)

49. Bohman M, Sigvardsson S, Cloninger CR: Maternal Inheritance of Alcohol Abuse: Cross-fostering Analysis of Adopted Women. Arch. Gen. Psychiatry, 38:965-969, 1981.

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50. Smith EM, Cloninger CR: Alcoholic Females: Mortality and Twelve-Year Follow-up. Focus on Women: Journal of Addiction and Health, 2:1-13, 1981.

Articles - 1982

51. Reich T, Cloninger CR, Suarez B, Rice J: Genetics of the Affective Psychoses. In:Handbook of Psychiatry, Vol. 3 (JK Wing, L Wing, editors). Cambridge, University Press, pp. 1437-159, 1982.

52. Wetzel RD, Cloninger CR, Guze SB The Assessment of Patients with Neurosis. In Burdock, EJ, Sudilovosky A, Gershon S (eds). Quantitative Techniques for the Evaluation of the Behavior of Psychiatric Patients, New York, Dekker, Chapter 18, pp. 439-484, 1982.

53. Cloninger CR, Rice J, Reich T, and McGuffin P: Genetic Analysis of Seizure Disorders as Multidimensional Threshold Characters. In Genetic Basis of the Epilepsies, edited by VE Anderson, WA Hauser, JK Penry, CF Cing, Raven Press, pp. 291-310, 1982.

54. Martin RL, Cloninger CR, and Guze SB: Alcoholism and Female Criminality. J Clinical Psychiatry, 43:400-403, 1982.

55. Cloninger CR, Sigvardsson S, Bohman M: Discriminant Analysis of Adoption Studies: A reply to Cadoret and Brier. Arch Gen Psychiatry, 39:974-975, 1982.

56. Cloninger CR: Contributions of Biogenetic Research to Classification of Psychiatric Disorders. Proceedings of WHO/ADAMHA Conference on International Diagnosis and Classification of Mental Disorders. WHO Publication, Geneva, 1982.

57. Bohman M, Cloninger CR, Sigvardsson S, von Knorring A-L: Predisposition to Petty Criminality in Swedish Adoptees. I. Genetic and Environmental Heterogeneity. Arch Gen Psychiatry, 39:1233-1241, 1982.

58. Cloninger CR, Sigvardsson S, Bohman M, von Knorring A-L: Predisposition to Petty Criminality in Swedish Adoptees. II. Cross-fostering Analysis of Gene-Environment Interaction. Arch Gen Psychiatry. 39:1242-1247, 1982.

59. Sigvardsson S, Cloninger CR, Bohman M, von Knorring A-L: Predisposition to Petty Criminality in Swedish Adoptees. III. Sex Differences and Validation of the Male Typology. Arch Gen Psychiatry. 39:1248-1253, 1982.

60. Martin R, Cloninger CR, Guze S: The Natural History of Somatization and Substance Abuse in Women Criminals: A Six Year Follow-Up. Comprehensive Psychiatry, 23:528-537, 1982.

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61. Lewis CE, Helzer J, Cloninger CR, Croughan JL, Whitman B: Psychiatric Diagnostic Predispositions to Alcoholism. Comprehensive Psychiatry, 23:451-461, 1982.

Articles - 1983

62. Cloninger CR and Reich T: Genetic Heterogeneity in Alcoholism and Sociopathy. Genetics of Neurological and Psychiatry Disorders, edited by SS Kety, Raven Press, 1983, pp 145-166.

63. Bohman M, Cloninger CR, Sigvardsson S, and von knorring A-L: Gene-environment Interaction in the Psychopathology of Swedish Adoptees: Studies of the origins of alcoholism and criminality. In Childhood Psychopathology and Development, edited by SB Guze, FJ Earls, and JE Barrett, Raven Press, New York, 1983, pp. 265-278.

64. Cloninger CR: Drug treatment of antisocial behavior. In Psychopharmacology, Volume 1, edited by Graham-Smith DG, Hippius H, and Winokur G: Excerpta Medica, Amsterdam, pp 353-370, 1983.

65. Cloninger CR, Rao DC, Rice J Reich T, Morton NW: A Defense of Path Analysis in Genetic Epidemiology. Amer J Hum Genetics, 35:733-756, 1983.

66. Smith EM, Cloninger CR, Bradford S: Predictors of Mortality in Alcoholic Women: A Prospective Follow-Up Study. Alcoholism: Clinical and Experimental Research, 7:237-243, 1983.

67. Cloninger CR, Reich T, Yokoyama S: Genetic Diversity, Genome Organization, and Investigation of the Etiology of Psychiatric Diseases. Psychiatric Developments, 3:225-246, 1983.

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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

Index No. 110951/96, Judge Charles E. Ramos

MARY ANN HOSKINS, Executrix of the Estate of Edwin Paul Hoskins, WALTINA BROWN and DANTE AUBAIN, individually, and on behalf of others similarly situated,

Plaintiffs,

- against -

R.J. REYNOLDS TOBACCO COMPANY, RJR NABISCO, INC., COUNCIL FOR TOBACCO RESEARCH-USA, INC., AND TOBACCO INSTITUTE, INC.,

Defendants

DECLARATION AND EXPERT'S REPORT OF C. ROBERT CLONINGER, M.D.

1. My name is C. Robert Cloninger, and I am a medical doctor and the Wallace Renard Professor of Psychiatry at Washington University School of Medicine. I am currently licensed to practice medicine in the State of Missouri and I am Board Certified in Psychiatry. I serve as a psychiatric consultant to the American Psychiatric Association, World Health Organization, and National Institutes of Health, and am active in clinical research on the pathogenesis, diagnosis, and treatment of substance dependence. A copy of my curriculum vitae is attached to this report.

2. I have been asked by attorneys representing R.J. Reynolds Tobacco Co. to review materials about Edwin Paul Hoskins,

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Waltina Brown, and Dante Aubain and the claim that they have been addicted to cigarette smoking in the case Hoskins, et al v. R.J. Reynolds Tobacco Company, et al. Further, I have been asked to express my medical opinions about their possible addiction to cigarette smoking based on these materials and my expertise on substance dependence for over twenty years. I have been asked to review the proposed definition of a class of persons similarly situated and the opinions of Michael Fiore and Jack Henningfield as designated experts in this case also. I may also be asked to comment on additional materials and testimony as they become available, including possibly testimony at trial.

3. I have reviewed the following materials about Edwin Paul Hoskins, Waltina Brown, and Dante Aubain:

   a) Regarding Edwin Paul Hoskins, transcripts of the oral deposition on 7/10/96, videotaped deposition on 7/11/96, volumes I and II;

   b) Regarding Waltina Brown, transcripts of depositions taken on 10/9/96 and on 8/8/97;

   c) Regarding Dante Aubain, transcripts of depositions taken on 10/10/96 and on 8/8/97 in the aforementioned case.

4. I have also reviewed the expert disclosure reports of Michael C. Fiore and of Jack E. Henningfield submitted to

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defendants' counsel by the attorneys for plaintiffs. Among their assertions are the claims that cigarettes and other forms of tobacco are "addicting" and "dependence-producing", that nicotine is the drug in tobacco that causes addiction, and that the pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine. They assert that smokers who try to quit are unable to do so because of nicotine's drug-like effects. They also assert that the plaintiffs' proposed class definition accurately identifies nicotine dependent smokers to a reasonable degree of medical certainty.

5. The plaintiff's proposed class definition would include all residents of New York who sometime after June 1980 became or continued to be dependent on nicotine. Nicotine dependence is defined to include those individuals either (1) diagnosed by a health professional as dependent on nicotine or (2) for a period of three years have smoked 16 cigarettes per day and generally have smoked the first cigarette within a half-hour of awakening. In my opinion, their proposed definition of a class fails to distinguish smokers who they claim are unable to quit smoking because of the drug-like effects of nicotine from other smokers who exercise their voluntary and legal choice to purchase

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cigarettes in order smoke tobacco for their personal enjoyment, cognition-enhancement, and/or stress-reduction. The plaintiffs are falsely assuming that all repetitive use of cigarettes meeting their class definition is a drug addiction, rather than a choice about personal habits, like other lifestyle choices such as exercise, diet, and recreation. The 1964 Surgeon General's Report on Smoking distinguished between habituation and addiction, whereas the 1988 Surgeon General's Report failed to make any distinction between addiction and the much broader concept of dependence, which can include habits or addictions.

Historically, the term addiction has been utilized by scholars, scientists, researchers, clinicians, politicians, bureaucrats and lay people to describe a wide variety of concepts. At the present time, the scientific community, government agencies, and the general public may at times use the term "addiction" to include such voluntary repetitive activities as frequent intake of chocolates, fatty foods, or salty potato chips, or preoccupation with sexual activity, as well as cigarette smoking. Sometimes the distinction is made between voluntary choice of habits versus addiction as a loss of control or compulsive use contrary to what the person wants to do. Actually, the term addiction is no longer sanctioned by any official medical system of

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classification at the present time. Most recently both the WHO and APA have utilized the term "dependence" to recognize not a simple syndrome but a complex interplay of psychological, social, and biological factors in substance use behavior. In the fourth and latest edition (1994) of American Psychiatric Association's Diagnostic and Statistical Manual, substance dependencies are further specified as "with physiological dependence" and "without physiological dependence". Dependencies without physiological dependence correspond to what have traditionally been considered "habits". Dependencies with physiological dependence, manifest by tolerance or withdrawal, may or may not correspond to what has been called an addiction.

As described in the 1964 Surgeon General's Report on smoking, a substance is traditionally considered to be addictive only if it causes

(a) intoxication manifest by impaired cognition and judgment,

(b) default of social and occupational responsibilities,

(c) physical dependence manifest by a consistently reproducible withdrawal syndrome, and

(d) tolerance to pleasurable effects.

According to these criteria, it is doubtful that tobacco or nicotine should be classified as addicting because

(a) it does not cause intoxication with impairment of

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cognition or judgment, (b) even heavy smokers are able to maintain their social and occupational responsibilities without difficulty, (c) abstinence produces either no withdrawal symptoms or at most mild anxiety symptoms, and (d) individuals maintain enjoyment of smoking the same number of cigarettes for many years.

Drug dependence is a much broader concept than drug addiction. The evolution of the nicotine dependence criteria in the *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition (*DSM-IV*) is especially problematic because the properties of nicotine are not as clearly defined as those of narcotics, alcohol, or cocaine. The first time a diagnosis for "tobacco dependence" appeared in the *Diagnostic and Statistical Manual* (*DSM*) was in the third edition (*DSM-III*) which was published in 1980. The earlier editions of *DSM* included diagnoses for other substance use dependencies but no such diagnosis for tobacco use. The inclusion of a diagnosis for "tobacco dependence" and later (1987) for "nicotine dependence" has been the subject of much controversy within the profession. The criteria for making the diagnosis changed from the original criteria in *DSM-III* when a revision was published in 1987, that being *DSM-III-R*, and changed still again with the recent publication this year of *DSM-IV*. Throughout this

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period, the changes in diagnostic criteria reflected the existence of widespread disagreement within the substance abuse community over the standards to define a dependence to tobacco. Moreover, the changes in diagnostic criteria have reflected tension over whether dependence is physical in nature or solely psychological in nature. In 1988, the Surgeon General chose to use the term addiction in his public health statements about tobacco and nicotine, even though many scientists and medical practitioners regard that term as overly simplistic, pejorative, and therapeutically counterproductive in clinical practice. The oversimplified model that the failure of smokers to quit is caused by the drug-like effects of nicotine is inadequate for clinical practice or public health policy because the desire to smoke is a learned habit that is determined by many individual personal and social factors and is not attributable simply to nicotine levels. For example, nicotine levels do not predict success in stopping smoking, and nicotine replacement therapy does not reduce the desire or urge to smoke. Self-directed regulation of lifestyle goals is the major determinant of success in stopping smoking. Accordingly, it is counterproductive to give people an excuse for their decision not to stop smoking by saying that they are addicted to nicotine when the major

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determinant of successful cessation is the personal decision and commitment not to smoke.

The plaintiffs' definition of nicotine dependence does not satisfy current medical standards for the diagnosis of dependence. Use of sixteen cigarettes a day with consumption of the first cigarette within a half hour of awakening is a simplification of the Fagerstrom criteria for nicotine dependence. However, neither this simplification nor the full Fagerstrom criteria are predictive of success in efforts to quit smoking. Even research carried out by the plaintiff's expert Dr. Fiore (JAMA 1994; 271:589-594) showed that pretreatment markers of nicotine dependence, such as the Fagerstrom Tolerance Questionnaire score, number of cigarettes smoked per day, years smoked, expired air carbon monoxide level, or blood nicotine and cotinine levels, showed no consistent relationship with successful smoking cessation. Likewise, most daily smokers are able to reduce or to stop smoking abruptly without nicotine replacement and without suffering impairment in their ability to work or other recreation. The occurrence of withdrawal symptoms is related to general traits of pessimism and anxiety-proneness, which reflect personality and psychological expectations, rather than on nicotine levels or variation in the quantity, frequency, and duration of smoking. Thus, the diagnosis of nicotine dependence, by any criteria, is inadequate to predict

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whether someone is able to stop smoking or not, and is certainly unable to distinguish individual smokers who cannot stop smoking because of alleged nicotine addiction from smokers who chose to continue smoking based on a decision that the satisfactions outweigh the risks.

The decision to continue smoking or to stop smoking depends strongly on voluntary personal choice. Although about 75% of current smokers say that they would like to stop or reduce their smoking, many fewer are actually committed to stopping. In a recent survey of 189 current smokers who said that they would like to stop smoking that I conducted as part of a study of personality and life style choices in the general population, only 84% of these thought it was practical for them to try at present, 58% had made a definite decision to try soon, 46% said that they were prepared to do whatever it takes to stop, and only 31% had a definite plan to carry out their intentions. Such differences in self-directed motivation to regulate smoking are similar to individual differences in the motivation to exercise more, to eat healthier (more vegetables, fewer sweets and fats), to lose weight, and to reduce life stress.

In other words, people smoke for very different reasons, they smoke in very different patterns, their motives to quit are very different and their efforts to quit are very different. There is simply no universal set of criteria which accurately classifies patterns of

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quit are very different. There is simply no universal set of criteria which accurately classifies patterns of smoking behavior for each and every individual smoker.

7. Available materials document the following facts about Mr. Hoskins's life history. Mr. Hoskins began smoking at age 14 years in 1944 and was smoking about half a pack (10) cigarettes daily when he entered Cornell University at the young age of 16 years. When he entered military service at age 20 he began smoking a pack a day and continued that thereafter until he quit at age 64 in 1994. He normally would not smoke in bed unless he was anxious and usually would not smoke until he had coffee in the morning (7/11/96, page 30). He worked as an attorney and was informed about the serious health risks of cigarettes including cancer. For example, his brother told him about the risks of cigarette smoking when the brother stopped smoking in 1952 after reading a Reader's Digest article on the health risks of cigarettes. Likewise, his children urged him to stop smoking during the 1970s and 80s for sake of his health. Despite such warnings, he stated that he was "my own best judge on lifestyle" (7/10/96, page 32). However, he also stated that he was dependent or addicted to smoking by age 15 (7/11/96, p 70) or age 25 (7/11/96, p 41) when he was smoking a pack a day, meaning that he could "no longer control myself when it came to smoking

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cigarettes" (7/10/96, page 76). However, at the time he says he was "hooked", he thought he could control his smoking (7/11/96, page 41) and actually he did stop for about a month in the mid-50s. He and his wife cut down, then stopped smoking: "It worked pretty good, but when we went back to the Legion and Rotary club, everyone was still smoking, and next thing we knew, we were right back where we started from" (7/11/96, page 32). As a result of the urging of his children (Vol 1, pages 66 and 67), again in the 1980s he quit for three weeks without problems, "felt pretty good", but then started smoking when watching others smoke around him. At his children's urging, again he quit for four months in 1985, felt good after quitting, but started again because he felt an urge to smoke. He found reducing and then stopping smoking on his own more effective than other methods like hypnosis, Cigarrest, and American Cancer Society cessation programs. He did not seek psychiatric, medical, or psychological treatment for cessation because he felt he could reduce and stop on his own without professional help (7/11/96, page 83). He didn't seek professional help because "I liked smoking and didn't really feel that shrinks would do any good" and only he could decide whether to make an attempt to stop (7/11/96, page 96). He picked his type of cigarette based on what he liked, rather than on tar or nicotine levels, advertisements, or warnings from others including his wife,

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doctor, and the US Surgeon General in 1964 and 1988 (7/11/96, pages 59-68 and 77). He reported that he was first aware that he was addicted in 1994 and yet it was around that time that he stopped permanently by his own volition on medical advice when diagnosed with Diabetes and abdominal cancer. After quitting he still had an urge to smoke, which he overcame because of health concerns (7/11/96, page 35 & 36). The same doctor (Dr. Benham) who advised him to stop smoking diagnosed him as an alcoholic, and advised him not to drink any more because most of his medical problems stemmed from his alcoholism (Vol II, p 92). Mr. Hoskins admits to drinking daily after work, but denied that his daily drinking was ever out of control or interfered with his work (Vol I, 7/11/96, page 101-103; Vol II, page 94).

8. On the basis of available materials, I have the following opinions about Edwin Hoskins's psychiatric history.

a) He was an intelligent, well-informed attorney, who was highly self-directed. He chose to smoke from age 14 to age 64 because he liked it, and he felt he could stop at any time he wanted to do so. At age 64 he took the position that he had been addicted without knowing it, but was in fact able to quit smoking successfully even then in response to medical advice. At age 64 and at previous occasions when he quit in the past for 3 weeks

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and for 4 months at the urging of his children, he was able to quit without any impairment from withdrawal symptoms. He quit smoking in the 80s at the urging of his children, but restarted in response to seeing others smoke because he also enjoyed smoking.

(b) There is no evidence of severe mental defect that impaired his capacity (competency) to make his own decisions voluntarily. In my opinion, he meets the class definition proposed by plaintiffs for nicotine dependence, but nevertheless could have quit smoking anytime he decided to do so. He was responsible for his voluntary decision not to quit entirely before 1994, and in fact eventually decided to quit and did so successfully in 1994.

9. Available materials document the following facts about Waltina Brown's psychiatric history. Ms. Brown reported that she began smoking at age 18 years when she went to college at Winston-Salem Teachers College in September 1957, and she quit successfully on June 19, 1995 on medical advice after a stroke (10/9/96, pages 13-15). The frequency of her smoking according to medical records is half-pack daily, but she claims since entering into litigation that she smoked one and one-half pack daily, only reducing to a half-pack per day when she had trouble breathing (1996, pages 92-93). She also claimed to have read about work by Dr. Fiore in the

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newspapers in the early 1980s in which nicotine addiction was defined as sixteen cigarettes daily with smoking within a half-hour of awakening (1996, pages 105-106); in contrast, Dr. Fiore's relevant publications date to the 1990s and he suggested the described criterion for dependence as part of this litigation in an affadavit provided to Mrs. Brown by the attorneys who solicited her as a possible class representative. She also claimed that she had regarded her smoking as a habit that was hard to quit until she heard about nicotine addiction during the testimony of Jim Johnson comparing cigarettes and Twinkies in 1994 (1996, pages 103-104, 164, 172). She reports she first quit smoking for a six month period in 1969 around the time of her pregnancy and breast feeding, but resumed smoking when she began socializing again (1996, page 42). She reports that she had symptoms of nervousness, anxiety, teary eyes, sleeping problems, and bronchitis throughout the entire six months she stopped (1996, pages 40-43). Her being "slightly anxious" after abstinence for two or three days is documented in medical records in 1993 (1996, page 95). She reported quitting other times in the 1980s for a week or two when she had bronchitis, usually cutting down gradually on cigarettes and eating candy more (1996, page 55 and 100). She never sought professional help for smoking cessation (page 116). She does consistently state that she stopped smoking entirely in June 19, 1995 on medical advice by her

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own volition.

10. On the basis of the available information, there are many inconsistencies in the plaintiff's statements, which make it difficult to be confidant that she is a valid member of the proposed class. The most consistent documentation in medical records is that she smoked only a half-pack daily. Other statements, such as her claims about reading about Dr. Fiore's work at a time when he had not done it, raise questions about the reliability of her reports. This illustrates the problems of delimiting a class without critical review of documentation in individual cases.

11. Available information document the following facts about Mr. Dante Aubain's psychiatric history. Mr. Aubain had his first cigarette at age 10 in 1948 and became a regular smoker at age 16 in 1954, smoking a pack a day (1996, page 15). He increased to two packs a day for about six years until 1975 (1996, page 65). He stated that he knew in high school that smoking was a "bad habit", which meant to him that it was "not good for you or bad for you or you couldn't stop doing it" (1996, page 55), like an addiction which was "something you got involved with that you could not stop" (1996, page 53). His doctor advised him to stop smoking repeatedly but he did not because the "Attorney General said it wasn't bad for

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Dante Aubain, it was bad for people." (1996, page 77). Mr. Aubain stated that he did not think it was impossible to quit smoking (page 89), and he was successful in quitting for more than one year around 1990-1991. He attended a seminar by a hypnotist and stopped for more than one year in order to qualify for lower life insurance rates (1996, page 102). He reported being irritable and tense for about one month, but he succeeded because he had a reason that encouraged him to succeed. After he passed the insurance test, a few months later he decided to smoke again (1996, page 103). Without the incentive of a lower insurance rate, attending the hypnotist seminar on other occasions was not successful. He has not tried nicotine patches because he says he is "lazy, did not have the incentive to stop smoking, or want to stop smoking" (page 112). He has not asked for professional help from a doctor to stop smoking because "I just felt I wasn't ready to stop smoking" (page 114). He drinks ten cups of coffee daily, but says he has never been diagnosed as dependent on coffee or other substances (page 151). Most recently he is still smoking a pack per day (1997, page 12). He has not sought professional assistance in smoking cessation, nor has he made any detailed plan to change his lifestyle in a way that would help him stop (1997, pages 14-16).

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12. Based on available information, I have formed the following opinion's about Mr. Aubain's psychiatric history. Mr. Aubain is an intelligent, well-informed individual with no evidence of a major mental defect that interferes with his capacity to make decisions or regulate his own life. He likes to smoke and his incentive to stop has been weak except when he desired a lower life insurance rate. With that incentive, he was able to successfully stop smoking for over a year, and only resumed smoking when that incentive was no longer operative. This clearly illustrates that difficulty stopping smoking depends on the personal goals and values of the individuals. In other words, the decision to continue or to stop smoking is under voluntary control of individuals who satisfy the plaintiff's proposed definition of a class of nicotine dependent individuals. Despite daily smoking, Mr. Aubain was fully able to stop smoking in order to qualify for a better life-insurance rate.

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13. All payments for my consultation in this case are made to Washington University Department of Psychiatry at the standard departmental rate of $300 per hour. I have provided 26 hours consultation beginning September, 1997.

C. Robert Cloninger

C. Robert Cloninger, M.D.

10/13/97

Date

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CUR[redacted]TAE

C. Robe[redacted]r, M.D.

Date: September, 1997

Birthplace: Beaumont, Texas

Citizenship: U.S.A.

Address: Office: Department of Psychiatry
Washington University Medical School
4940 Children's Place
St. Louis, MO 63110
314-362-7005 (phone)
314-362-5594 (fax)

Home: 7100 Delmar
University City, MO 63130
314-863-1338

Present Position: Wallace Renard Professor of Psychiatry, also Professor of Genetics & Psychology, and Director of Center for Psychobiology of Personality

Education:

University of Texas, Austin, Texas, 1962-1966, B.A. with high honors and special honors in Plan II (Philosophy, Psychology, and Anthropology).

Washington University School of Medicine, St. Louis, MO 1966-1970, M.D.

Epidemiology Field Research Trainee, California State Department of Public Health, Berkeley, California, July 1967-September 1967.

Student Research Fellow (with S.B. Guze), Washington University School of Medicine, St. Louis, Missouri, June 1969-October 1969.

Assistant Resident-Assistant and Trainee (NIMH) in Psychiatry Washington University School of Medicine, St. Louis, Missouri, July 1970-June 1973.

Research Scientist Development Awardee (NIMH) in Quantitative Genetics, July 1975-1985.

Visiting Investigator, Population Genetics Laboratory, University of Hawaii at Manoa, July 1978-June 1979.

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Academic Positions/Employment:

Instructor in Psychiatry, Washington University School of Medicine, St. Louis, Missouri, July 1973-June 1974

Assistant Professor of Psychiatry, Washington University School of Medicine, St. Louis, Missouri, July 1974-June 1978.

Associate Professor of Psychiatry, Washington University School of Medicine, St. Louis, Missouri, July 1978-June 1981.

Associate Professor of Genetics, Washington University School of Medicine, St. Louis, Missouri, July 1979-June 1981

Visiting Professor of Psychiatry and Genetics, University of Umea School of Medicine, Umea, Sweden, May to June, 1980.

Professor of Psychiatry and Genetics, Washington University School of Medicine, July 1981-Present.

Head, Department of Psychiatry, Washington University School of Medicine, July 1989-March 1994

Professor of Psychology, Washington University, July 1989-present.

Wallace Renard Professor of Psychiatry, Washington University, July 1991-present

Director, Center for Psychobiology of Personality, March 1994-present

Hospital Appointments:

Barnes and Allied Hospitals, St. Louis, MO
- Assistant Psychiatrist, July 1973-June 1980
- Associate Psychiatrist, July 1980-June 1981
- Psychiatrist, July 1981-present
- Psychiatrist-in-chief July 1989-March 1994

Children's Hospital of St. Louis
- Psychiatrist-in-chief, July 1989-June 1991

Malcolm Bliss Mental Health Center, St. Louis, MO
- Consulting Psychiatrist, July 1973-1989

Jewish Hospital of St. Louis, MO
- Associate Psychiatrist, July 1976-June 1980
- Psychiatrist, July 1980-Present
- Director of Outpatient Psychiatry, July 1976-June 1989

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Other University Appointments and Committees:

Steering Committee Member, McDonnell Center for Higher Brain Function, 1989 - 1993

Steering Committee Member, WUMS Howard Hughes Program, 1990 - 1993

Chair, Division of Biostatistics Advisory Committee, 1989 - 1993

Member, Health Care Administration Advisory Committee, 1989 - 1993

Member, Occupational Therapy Program Advisory Committee, 1990 - 1993

Medical Licensure and Board Certifications:

State Board of the Healing Arts of Missouri, Physicians and Surgeons #32703, issued June 20, 1970

Missouri Controlled Substance Registration #210508

Bureau of Narcotic and Dangerous Drugs #AC4359419

Diplomate, American Board of Psychiatry and Neurology, 1975

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Honors and Awards:

Institute of Medicine, National Academy of Sciences, USA, elected active member, May 1989 - present

Fellow, American Association for the Advancement of Science, 1996- present, for outstanding contributions in the field of psychiatry, especially alcoholism and personality disorders

Phi Beta Kappa - 1965

Phi Beta Sigma - 1963

Alpha Epsilon Delta - 1965

Sandoz Award for Research in Psychiatry, Washington University School of Medicine (1970)

Research Scientist Development Awards:

Type 1 (1975-1980) MH-0048. The transmission and prognosis of psychiatric disorders (Quantitative Genetics and Environmental Genetic Interaction)

Type 2 (1980-1985) Genetic epidemiology of psychiatric disorders

Research Scientist Award (MH-00048)
Genetic Epidemiology of Psychiatric Disorders (1985-1989)
(Resigned to accept chairmanship)

Endowed Visiting Professorships

Milton and Harriet Parker Memorial Lecturer, Ohio State University, Department of Psychiatry, September 1983 and December 1985

John Nielson Distinguished Lecturer, University of Utah, Department of Psychiatry, April 1988

Stewart Wolf Distinguished Lecturer, University of Oklahoma, Department of Medicine, May 1988

James Brady Lecturer, University of Colorado, 1989

Frank H. Luton Lecturer, Vanderbilt University, 1989

William D. Stubenbord Visiting Professor, Cornell University Medical College and the Louis Calder Foundation, September, 1991

Other Distinguished Lectureships

Sigma Xi Lecturer on Natural Sciences, University of North Carolina, October 1987

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NIH Centennial Lecturer, Washington, DC, September 1987

Plenary Lecturer, Research Society on Alcoholism, June 1988

Pfizer Visiting Professor, Columbia University and New York State Psychiatric Institute, October 1991

Gudbrandsdalen Medalist & Lecturer, Norwegian Medical Research Council, Lillehammer, Norway, 1992

Keynote Speaker, Australian-New Zealand Psychiatric Association Annual Meeting, Christchurch, New Zealand, 1993 and 1996

Lederle Visiting Professor, Hospital de la Salpetriere, Paris, France, December, 1993

Plenary Lecturer, Japanese Society of Psychosomatic Medicine, Kyoto, Japan, 1996

Plenary Lecturer, American College of Psychiatry, Kauai, Hawaii, 1996

Charles E. Smith Lecturer, National Institute for Psychobiology in Israel, Hebrew University, Jerusalem, Israel (Psychobiology of Human Personality), March 5, 1998

Honorary Doctor of Medicine (M.D. honoris causa), University of Umea (Sweden), October 1983 for distinguished contributions to genetic epidemiology of psychiatric disorders

Strecker Award (The 25th Annual Institute of Pennsylvania Hospital Award in Memory of Edward A. Strecker, M.D.), 1988 for significant contributions to psychiatric patient care and treatment by studies of the assessment and inheritance of personality and psychopathology

Edgehill Newport Scientific Recognition Award, May 1990, in recognition of outstanding contributions to the treatment of chemically dependent persons through basic research

Mortimer Goodman Memorial Award, The Alliance for the Mentally Ill of Metro St. Louis, in recognition of outstanding service as a physician, researcher, administrator, public servant and friend, May 1992

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James B. Isaacson Memorial Award, June 1992, International Society for Biomedical Research on Alcoholism and National Foundation for Prevention of Chemical Dependency Disease, for excellence in scientific research into the causes of chemical dependency diseases

Samuel Hamilton Award, March 1993, American Psychopathological Association, for contributions to understanding personality and psychopathology

Adolf Meyer Award, May 1993, American Psychiatric Association, for outstanding contributions to the science and practice of psychiatry

Editorial Responsibilities:

Editor, Behavior Genetics (1980-1986)
Associate Editor,
American Journal of Human Genetics (1980- 1983)
Journal of Clinical Psychiatry (1981-1987)
Genetic Epidemiology (1983-1991)
Human Heredity (1989-Present)
Field Editor, Neuropsychiatric Genetics, American Journal Medical Genetics (1992 -)
Editorial Boards,
Archives of General Psychiatry (1987-)
Neuropsychopharmacology (1991-)
Comprehensive Psychiatry (1992-)
Journal of Psychiatric Research (1993-)
American Journal of Medical Genetics (1993 -)
Psychiatric Genetics (1993 -)

Professional Societies and Organizations:

Advances in Neuropyschiatry and Psychopharmacology
Editorial Board - Raven Press (1991-1993)

American Association for the Advancement of Science, Member (1976-Present)

Representative of the Behavior Genetics Association Section Committee for Medical Sciences (Section N) (1986-1989)

American College of Neuropsychopharmacology, Member (1987-)
Committee on Issues of Public Concern (1988- 1997)

American Medical Association, Member (1982-Present)

American Psychiatric Association, Member (1975-1979)
Fellow (1980-Present)

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American Psychopathological Association, Fellow (1976-Present)
Membership Chairman (1978-1984)
Treasurer (1984-1990)
Vice-President (1990-1991)
President-Elect (1991-1992)
President (1992-1993)

American Society of Human Genetics, Member (1976-Present)

Behavior Genetics Association, Member (1976-Present)
BGA Representative to AAAS Section Committee for Medical Sciences
Chairman, Publications Committee (1986-1989)

Center for Advanced Study in the Behavioral Sciences, Academic Psychiatry Consortium
(1990-1993, 1993-1996)

Eastern Missouri Psychiatric Society, Member (1973-Present)

International Society for Study of Personality Disorders,
Board of Directors - (1991 -)
President, American Region - (1993 -)

Psychiatric Research Society, Member (1977-Present)

Research Society on Alcoholism (1981-Present)
Committee on Research Development (1984-Present)
Member, Board of Directors (1987-1990)
Committee on Issues of Public Concern (1989-91)

Society of Biological Psychiatry, Member (1977-Present)

Consulting Relationships and Board Memberships:

Consultant, American Psychiatric Association
Task Force on Nomenclature (Diagnostic and Statistical Manual - III), 1978-1980
Task Force to Evaluate DSM-III, 1983-
Committee to Revise DSM-III, 1984-1987
Task Force on DSM-IV, 1988-

Psychiatric Consultant and Member of Professional Advisory Council, Suicide Prevention Service of Madison - St. Clair Counties (1971-1993)

Psychiatric Consultant, 3rd Judicial Circuit of Illinois (1973-1974)

Special Consultant and Site Visitor, NIMH Clinical Program Projects and Clinical Projects Review Committees (1977-1980)

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NIMH Psychopathology and Clinical Biology Research Review Committee:
Consultant and Committee Member (1980-Present)
Chairman, Psychopathology Subcommittee (June 1981-1983)
Chairman (June 1983-July 1984)

Scientific Advisor and Consultant, NIMH Affective and Anxiety Disorders Research Branch (1986-1989)

Scientific Advisory Board
Children of Alcoholics Foundation (1989 - present)

Consultant to Director, NIAAA (1984-1997)
Board of Scientific Counselors (1988-1992)

Consultant, World Health Organization (WHO)/ADAMHA Advisory Group on Diagnosis and Classification of Mental Disorders, and Alcohol - and Drug-Related Problems (1981-1985)
Consultant Psychiatrist (1993-present)

Member, Research Advisory Council, Texas Department of Mental Health and Mental Retardation (1983-1985)

Extramural Scientific Advisor and Consultant
Chicago Medical School, Department of Psychiatry (1977)
New York University Medical School, Psychiatry (1980-82)
University of Minnesota, Dight Laboratories, Genetics (1985-88)
University of Connecticut, Alcoholism Research Center (1986-91)
University of Pennsylvania, Clinical Research Center (1987-present)
University of Colorado, Alcohol Research Center (1991-)

University of Oklahoma,
Alcoholism Research Center (1987-92)

Honorary Member - IBC Advisory Council, 1989

Scientific Advisory Board - Oklahoma Center of Molecular Medicine, 1990

Missouri Mental Health Commission - (9/26/90 - 6/28/94)

Pfizer Visting Professorship in Psychiatry Academic Advisory Committee, 1993-1996

Science Advisory Board, Treatment and Research Advancements Association for Personality Disorder - (1997 -)

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Research Support:
Governmental:

NIMH, MH31302, Epidemiological Genetics and Family Study, C.R. Cloninger, M.D., P.I.; 08/01/86 - 07/31/2001

NIAAA, AA07982, Prediction of Alcohol Abuse in Swedish Adoptees, C.R. Cloninger, M.D. P.I.; 07/01/88 - 06/30/95

NIAAA, AA08028, Molecular Genetic Studies of Alcoholic Subtypes, C.R. Cloninger, M.D., P.I.; 12/01/88 - 11/30/95

NIMH, MH46276, Diagnostic Center for Linkage Studies of Schizophrenia, C.R. Cloninger, M.D., P.I.; 09/30/89 - 08/31/94

NIAAA, AA08401, Collaborative Studies on the Genetics of Alcoholism, Coordinating Center, Theodore Reich, M.D., P.I.; 10/01/89 - 09/30/94

NIMH, MH46280, Diagnostic Center for Linkage Studies of Bipolar Disorder, Theodore Reich, M.D., P.I.; 09/30/89 - 08/31/94

MH14677, Research Training in Clinical Sciences, C.R. Cloninger, M.D., P.I.; 07/01/92 - 06/30/97 (transferred to T. Reich, 7/1/93)

Teaching Titles and Responsibilities:

Coursemaster, Introduction to Clinical Psychiatry - Washington University School of Medicine II (1976-1989)

Committee on Academic Review and Promotion (1976-1989)

Lecturer, Medical Genetics, Washington University School of Medicine (1980-Present)

Clinical Sciences Postdoctoral Training Program
Preceptor (1975-Present)
Psychiatric Genetics Director (1980-Present)
Overall Program Director (1985-1993)

RESEARCH TRAINEES

Betty Lobos, B.S., Predoctoral Graduate Student (1985-1993)
Training: Quantitative and molecular genetics.
Dissertation Topic: Genetics of Nicotine Acetylcholine Receptor.

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Sean Yutzy, M.D., Postdoctoral Fellow, (1990-1992)
Training: Nosology of somatoform and personality disorders
Currently: Assistant Professor of Psychiatry, Washington University School of Medicine

Dragan M. Svrakic, M.D., Ph.D., Fulbright Scholar from University of Belgrade, Yugoslavia (Sept 88-Aug 89)
Training: Collaboration on Cross-cultural studies of personality assessment and structure.
Currently, Assistant Professor of Psychiatry, Washington University School of Medicine

Stephen Dinwiddie, M.D., Postdoctoral Fellow (1987-1990)
Training: Clinical and genetic methods for studying neuroadaptive processes in substance abusers.
Currently: Assistant Professor of Psychiatry, Washington University School of Medicine

Ronald Martin, M.D., Psychiatry Resident, 1975-1977
Training: Supervised his follow-up of female felons I had previously studied; trained in conduct and analysis of longitudinal clinical studies
Currently: Professor & Chairman of Psychiatry, University of Kansas at Wichita.

Collins E. Lewis, M.D., M.P.H., Psychiatry Resident, 1975-1977
Training: Supervised clinical and family study of alcoholics; trained in epidemiological methods and family studies.
Currently: Associate Professor of Psychiatry, Washington University.

William Coryell, M.D., Psychiatry Resident, 1977
Training: Supervised his participation in a reliability study of a new structured interview; trained in methods for conducting and interpreting reliability studies.
Currently: Professor of Psychiatry, University of Iowa.

John P. Rice, Ph.D., Postdoctoral Fellow, 1975-1977
Training: Directed reading about psychiatric genetics and genetic epidemiology; we jointly worked on extending methods for cultural inheritance and segregation analysis.
Currently: Professor of Psychiatry & Biostatistics, Washington University.

Andrew Scallet, Ph.D., Predoctoral Psychology Student, 1975-1976
Training: Supervised research on assessment and double-blind treatment studies of outpatients.
Currently: Research Psychologist, National Center for Toxicological Research, Jefferson, Arkansas

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Lenore Teter, M.D., Psychiatry Resident, 1980
Training: Supervised research on psychiatric social adjustment of recent Russian immigrants.
Currently: Instructor in Psychiatry, Washington University, then private practice

Robert Desalle, B.S., Predoctoral Genetics Fellow, 1979
Training: Method of path analysis in studying inheritance of complex phenotype systems.
Currently: Completed dissertation in Genetics, Washington University.
Currently: Department of Biology, Yale University

Peter McGuffin, M.D., Postdoctoral Fellow, 1980-1981
Training: Advanced methods of genetic epidemiology including segregation, path, admixture, and linkage analysis.
Currently: Professor & Chairman of Psychiatry, Cardiff, England

Paul Van Eerdewegh, Ph.D., Predoctoral Fellow, 1980-1982
Training: Studies of statistical properties of copaths and selection in multivariate systems relevant in quantitative genetics.
Currently: Assistant Professor in Psychiatry in Genetic Epidemiology, Washington University.

Dennis O'Rourke, Ph.D., Postdoctoral Fellow, 1980-1983
Training: Advanced methods of genetic epidemiology including segregation, path, and linkage analysis.
Currently: Professor of Anthropology, University of Utah.

Anne-Liss von Knorring, M.D., Postdoctoral Fellow, 1982-1983.
Training: Methods of genetic epidemiology relevant to adoption studies.
Currently: Professor of Child Psychiatry, University of Uppsala, Sweden.

Soren Sigvardsson, D. Med. Sci., Predoctoral Fellow, 1981
Postdoctoral Fellow, 1983
Training: Methods of genetic epidemiology and multivariate analysis relevant to adoption studies; longitudinal and cross-fostering studies of adoptees with relevance to child psychiatry.
Currently: Associate Professor of Child Psychiatry, Umea University.

Nancy J. Cox, Ph.D., Postdoctoral Fellow, 1982
Training: Advanced methods of genetic epidemiology for studying psychiatric disorders.
Currently: Assistant Professor, University of Chicago.

Eric Devor, Ph.D., Postdoctoral Fellow, 1982

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Training: Advanced methods of genetic epidemiology in anthropology; population structure.
Currently: Assistant Professor of Psychiatry, University of Iowa, Iowa City

Mark Zoccolillo, M.D., Psychiatry Resident, 1983
Training: Supervised design and analysis of clinical and social comparison of matched groups of outpatients with somatoform and affective disorders; study of parenting and home environmental influences on children of outpatients.
Currently: Assistant Professor of Psychiatry, Texas Tech

Edward Lauterbach, M.D., Psychiatry Resident, 1984
Training: Design and analysis of psychiatric follow-up studies.
Currently: Associate Professor of Psychiatry, (Tenure) Mercer University School of Medicine, Macon, Georgia

Kara Forest, B.A., Biology Honors Student, 1986
Training: Etiology of anxiety states.
Currently: Medical school

Wolfgang Baier, M.D., FRG Postdoctoral Fellow, 1987
Training: Genetic epidemiology of generalized minor seizures (collaborative project with Professor Doose at University of Kiel, FRG)
Currently: Child Neurologist, University of Kiel

David Craufurd, M.D., Wellcome Trust Fellow, 1987.
Training: Psychiatric Genetics.
Currently: Research Psychiatrist, St. Mary's Hospital, University of Manchester, England.

Sheila B. Gilligan, B.S., Predoctoral Graduate Student (1983-1988)
Training: Quantitative genetics of common diseases.
Dissertation Topic: Genetic and Phenotypic Heterogeneity in Alcoholism (scheduled to complete Spring, 1988).
Currently: Postdoctoral Fellow in Human Genetics, Medical College of Virginia (Dr. Andrew Heath), then Peace Corps in Africa.

Vicky Ryan, Undergraduate biology honors student (1987-1988)
Training: Techniques in family studies of alcoholism.
Currently: Medical School, University of Missouri

David L. Garver, M.D., Sabbatical Leave from University of Cincinnati, Depts. of Psychiatry and Pharmacology (Sept 88-Aug 89)
Training: Psychiatric genetics including clinical and molecular aspects.
Currently: Professor of Psychiatry, Southwestern Medical

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School, Dallas, Texas

Harald and Gabrielle Aschauer, M.D., Medical Research Council of Austria Fellows
Training: Neuropsychopharmacologist/psychiatrist coming for training in genetics of schizophrenia (Sept 87-March 1989).
Currently: Assistant Professors in Vienna

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Source: https://www.industrydocuments.ucsf.edu/docs/dtxl0091

Bibliography

Articles - 1970

1. Cloninger CR and Guze SB: Psychiatric Illness and Female Criminality: The Role of Sociopathy and Hysteria in the Antisocial Women. Amer. J. Psychiat., 127(3):303-311, 1970.

2. Cloninger CR and Guze SB: Female Criminals: Their Personal, Familial, and Social Backgrounds (The Relations of These to the Diagnoses of Sociopathy and Hysteria). Arch. Gen. Psychiat., 23:554-558, 1970.

Articles - 1973

3. Cloninger CR and Guze SB: Psychiatric Illness in the Families of Female Criminals: A Study of 288 First-Degree Relatives. Brit. J. Psychiat., 122:697-703, 1973.

4. Cloninger CR and Guze SB: Psychiatric Disorders and Criminal Recidivism: A Follow-up Study of Female Criminals. Arch. Gen. Psychiat., 29:266-269, 1973.

Articles - 1974

5. Hearst ED, Cloninger CR, Crews EL, and Cadoret RJ: Electrosleep Therapy: A Double Blind Trial. Arch. Gen. Psychiat., 30:463-466, 1974.

6. Cloninger CR: Group Rape: A Commentary. Med. Aspects of Human Sexuality, 8:81, 1974.

7. Cloninger CR, Packman PM, Cicero TJ, Boshans RL, and Robins E: Morphine Dependence and Enzyme Activity in the Hypothamus. Biochem. Pharmacol. 23:983-988, 1974.

Articles - 1975

8. Cloninger CR and Guze SB: Hysteria and Parental Psychiatric Illness. Presented at the Annual Meeting of APA, 1973. Psychol. Med., 5:27-31, 1975.

9. Reich T, Cloninger CR, and Guze SB: The Multifactorial Model of Disease Transmission: I. Description of the Model and its Use in Psychiatry. Brit. J. Psychiatry, 127:1-10, 1975. (Science Citation Index Citation Classic)

10. Cloninger CR, Reich T, and Guze SB: The Multifactorial Model of Disease Transmission: II. Sex Differences in the Familial Transmission of Sociopathy (Antisocial Personality). Brit. J. Psychiatry, 127:11-22, 1975.

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11. Cloninger CR, Reich T, and Guze SB: The Multifactorial Model of Disease Transmission: III. Familial Relationship Between Sociopathy and Hysteria (Briquet's Syndrome). Brit. J. Psychiatry, 127:23-32, 1975.

12. Cloninger CR: Recognizing and Treating Sociopathy. Medical World News, 16(23):12-18, 1975.

13. Cloninger CR, Reich T and Guze SB: Genetic-Environmental Interactions and Antisocial Behavior. In Psychopathic Behavior: Approaches to Research, (Eds. RD Hare and D Schallings). Proceedings of the NATO Advanced Study Institute on Psychopathic Behavior, Les Arcs, France. September 5-12, 1975. Chichester: John Wiley and Sons, 1978, pages 225-238.

14. Cloninger CR: The Link Between Hysteria and Sociopathy. Chapter 11 in Psychiatric Diagnosis: Exploration of Biological Predictors, Predictors in Psychiatric Diagnosis, Memphis, Tennessee, December 7-9, 1975. (Eds. HS Akiskal and WL Webb). New York: Spectrum, Inc. 1978, pages 189-218.

Articles - 1976

15. Scallet A, Cloninger CR, and Othmer E: The Management of Chronic Hysteria: A Review and Double Blind Trial of Electrosleep and Other Relaxation Methods. Dis. Nerv. System, 37(6):347-353, 1976.

16. Woodruff RA, Clayton P, Cloninger CR, and Guze, SB: A Brief Method of Screening for Alcoholism. Dis. Nerv. System, 37(8):434-435, 1976.

Articles - 1977

17. Hill S, Cloninger CR, and Ayre F: Independent Familial Transmission of Alcoholism and Opiate Abuse. Alcoholism: Clinical and Experimental Research, 1(4):335-342, 1977.

18. Guze SB, Akiskal HS, Cadoret R, Cloninger CR, Matthysse S, and Rosenthal D: Family and Genetic History as Diagnostic Predictors. Chapter 12 in Psychiatric Diagnosis: Exploration of Biological Predictors, op. cit., pages 219-233.

19. Liskow BI, Clayton P, Woodruff R, Guze SB, and Cloninger CR: Briquet's Syndrome, Hysterical Personality, and the MMPI. Amer. J. Psychiat., 134(10):1137-1139, 1977.

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Articles - 1978

20. Cloninger CR, Christiansen KO, Reich T, and Gottesman II: Implications of Sex Differences in the Prevalence of Antisocial Personality, Alcholism, and Criminality for Models of Familial Transmission. Arch. Gen. Psychiat., 35:941-951, 1978.

21. Martin RL, Cloninger CR, and Guze SB: Female Criminality and the Prediction of Recidivism: A Prospective Six Year Follow-up. Arch. Gen. Psychiat., 35:207-214, 1978.

22. Coryell W, Cloninger CR, and Reich T: Clinical Assessment: Use of Non-Physician Interviewers. J. Nerv. Ment. Dis., 166(8):599-606, 1978.

23. Powell C, Miller JP, and Cloninger CR: The Use of SAS for the Analysis of Family Studies. In Strand, RH (Ed.), Proceedings of the Third Annual Conference on the SAS User's Group International. SAS Institute, Inc., Raleigh, North Carolina, 1978, pp. 189-194.

24. Reich T, Cloninger CR, Lewis CE, and Rice J: Familial Structures in Models of Cultural Inheritance. In NE Morton and CS Chung (Eds.) Genetic Epidemiology. Academic Press, 1978, pp. 183-191.

25. Cloninger CR, Matthysse S, Anderson VE, and Morton NE: Panel Discussion: Resolution of Etiologic Heterogeneity in the Psychoses. In NE Morton and CS Chung (Eds.), Genetic Epidemiology. Academic Press, 1978, pp. 329-330.

26. Rice J, Cloninger CR, and Reich T: Multifactorial Inheritance with Cultural Transmission and Assortative Mating. I. Description and Basic Properties of the Unitary Models. Am. J. Hum. Genet., 30:618-643, 1978.

27. Cloninger CR: Antisocial Personality. Hospital Practice, 13(8):97-112, 1978. Reprinted in Guggenheim F, Nadelson CC (Eds.), Handbook of Major Psychiatric Disorders: Overviews and Selected Readings. Elsevier North Holland, pp. 169-178, 1982.

Articles - 1979

28. Cloninger CR, Miller JP, Wette R, Martin RL, Guze SB: The Evaluation of Diagnostic Concordance in Follow-up Studies: I. A General Model of Causal Analysis and a Methodological Critique. J. Psychiat. Research, 15:85-106, 1979.

29. Martin RL, Cloninger CR, Guze SB: The Evaluation of Diagnostic Concordance in Follow-up Studies: II. A Blind Prospective Follow-up of Female Criminals. J. Psychiat. Research, 15:107-125, 1979.

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30. Cloninger CR, Reich T, Wetzel R: Alcoholism and the Affective Disorders: Familial Association and Genetic Models. In: Alcoholism and the Affective Disorders (eds. D Goodwin and C Erickson). New York: Spectrum Press, pages 57-82, 1979.

31. Reich T, Rice J, Cloninger CR, Wette R, James J: The Use of Multiple Thresholds and Segregation Analysis in Analyzing the Phenotypic Heterogeneity of Multifactorial Traits. Annals of Human Genetics, London, 42(3): 371-390, 1979.

32. Cloninger CR, Rice J, Reich T: Multifactorial Inheritance with Cultural Transmission and Assortative Mating. II. A General Model of Combined Polygenic and Cultural Inheritance. Am. J. Hum. Genet., 31:176-198, 1979.

33. Cloninger CR, Rice J, Reich T: Multifactorial Inheritance with Cultural Transmission and Assortative Mating. III. Family Structure and the Analysis of Separation Experiments. Am. J. Hum. Genet, 31:366-388, 1979.

34. Rice J, Reich T, Cloninger CR, Wette R: An Approximation to the Probabilities of the Multivariate Normal Distribution: Its Application to the Multifactorial Model of Qualitative Traits. Biometrics, 35:451-459, 1979.

35. Rao DC, Morton NE, Cloninger CR: Path Analysis Under Generalized Assortative Mating. I. Theory. Genetical Research, Cambridge: 33:175-188, 1979.

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CUYAHOGA COUNTY, OHIO

313491

JUDITH E. CHAMBERLAIN, INDIVIDUALLY AND ON BEHALF OF HERSELF AND ALL OTHERS SIMILARLY SITUATED, 3237 Clarendon Road Cleveland Heights, Ohio 44118	CASE NO.:
and	
WILLIAM CRIDEN, INDIVIDUALLY AND ON BEHALF OF HIMSELF AND ALL OTHERS SIMILARLY SITUATED, 644 3rd Street, S.E. Massillon, Ohio 44646	CLASS ACTION COMPLAINT
Plaintiffs,	Jury Demand Endorsed Hereon
-v-	
THE AMERICAN TOBACCO COMPANY, INC. Six Stamford Forum Stamford, Connecticut 06904 c/o Statutory Agent CT Corporation Systems 441 Vine St., Suite #3810 Cincinnati, Ohio 45202	
and	
AMERICAN BRANDS, INC. 1700 East Putnam Ave. Old Greenwich, CT 06870 c/o Statutory Agent Prentice-Hall Corporation Systems 380 South 5th Street Columbus, Ohio 43215	

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Cincinnati, Ohio 45201

and

RISER FOODS INC.
Bedford Heights, Ohio 44146
c/o Statutory Agent
1600 CNB Corp.
1375 E. 9th Street
20th Floor
Cleveland, Ohio 44114

Defendants.

Individual and representative plaintiffs Judith E. Chamberlain and William Criden ("Plaintiffs"), on behalf of themselves and all others similarly situated (the "Plaintiff Class"), complain against Defendants as follows:

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I. NATURE OF THE CASE

1. Through a fraudulent course of conduct that has spanned decades and which continues unabated to this day and which is more fully described below: (1) Defendants have manufactured, promoted, marketed, supplied and sold cigarettes to millions of Ohioans, including Plaintiffs and members of the Plaintiff Class, while knowing, but denying and actively concealing, that their cigarettes contain a highly addictive drug known as nicotine, and (2) Defendants have controlled and manipulated the amount of nicotine in their cigarettes with the express purpose and intent of creating and sustaining addictions to cigarettes. In other words, to ensure that the corporate coffers continue to overflow, the Tobacco Industry has single handedly created a guaranteed marketplace for their products by enslaving generations of unwitting Ohioans through nicotine addiction.

This conspiracy of death and addiction, along with other wanton and willful acts of the Tobacco Industry, has directly harmed and damaged Plaintiffs and members of the Plaintiff Class. Plaintiffs and members of the Plaintiff Class seek compensatory damages for their economic losses, personal injuries, emotional distress as well as punitive and exemplary damages and equitable relief, including the establishment of a medical monitoring fund. These damages are sought to remedy violations by the Defendants of the common law doctrines of fraud, civil conspiracy, negligent misrepresentation; negligence; intentional infliction of emotional distress; negligent infliction of serious emotional distress;

product liability doctrines of strict liability and the breach of express and implied warranties; and, for violations of Ohio Revised Code, Chapter 1345 [Consumer Sales Practices] and Chapter 4165 [Deceptive Trade Practices].

II. VENUE

2. Venue is proper in this Court pursuant to Rule 3 of the Ohio Rules of Civil Procedure ("Civil Rules"). Certain Plaintiffs and members of the Plaintiff Class have purchased and continue to purchase cigarettes manufactured and sold in Cuyahoga County, Ohio by the Defendants. Defendants have advertised, marketed, supplied and sold cigarettes in Cuyahoga County and continue to advertise, market, supply and sell cigarettes in Cuyahoga County, Ohio. Defendants have received and continue to receive substantial compensation, income and profits from the sales of cigarettes in Cuyahoga County, Ohio.

III. PARTIES

A. Plaintiffs and Proposed Class Representatives.

3. For their Complaint, through the undersigned counsel, come (1) Judith E. Chamberlain and (2) William Criden, both of whom are persons of the age of majority domiciled in the State of Ohio and who further appear on behalf of those individuals similarly situated.

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4. Plaintiff and proposed class representative Judith E. Chamberlain, started smoking at the age of 14. In her efforts to quit smoking, Ms. Chamberlain attended various medical sessions at the Cleveland Clinic Foundation, tried sessions with a hypnotist, attended the anti-smoking program of the American Cancer Society and has otherwise attempted to "kick" her "nicotine habit" by using nicotine chewing gum and other various methods. However, due to her nicotine addiction, she has been unable to quit. Her addiction to cigarettes has caused her out-of-pocket expenses, mental and physical suffering, frustration, humiliation along with other damages which will be proven at trial.

5. Plaintiff and proposed class representative William Criden, started smoking at the age of fifteen and has tried on numerous occasions to discontinue the use of cigarettes, all to no avail. His addiction to cigarettes caused him out-of-pocket expenses, mental and physical suffering, and frustration and humiliation among other damages to be proven at trial.

B. Defendants.

6. Defendant The American Tobacco Company, Inc. and its parent, Defendant American Brands, Inc., are Delaware corporations whose principal places of business are located at Six Stamford Forum, Stamford, Connecticut. The American Tobacco Company and American Brands, Inc. manufacture, advertise, market and sell Lucky Strike, Pall Mall, Tareyton, Malibu, American, Montclair, Newport, Misty, Iceberg, Silk Cut, Silva Thins, Sobrania, Bull Durham and

Carlton cigarettes throughout the United States including the State of Ohio. On December 21, 1994, The American Tobacco Company was purchased by B.A.T. Industries P.L.C. who on information and belief has succeeded to the liabilities of the American Tobacco Co. by operation of law or as a matter of fact (collectively "American Tobacco").

7. Defendant R.J. Reynolds Tobacco Company is a New Jersey corporation whose principal place of business is located at Fourth and Main Streets, Winston-Salem, North Carolina. R.J. Reynolds Tobacco Company is a wholly-owned subsidiary of Defendant RJR Nabisco, Inc., a Delaware corporation, whose principal place of business is 1301 Avenue of the Americas, New York, New York. Defendants R.J. Reynolds Tobacco Company and RJR Nabisco, Inc. manufacture, advertise, market and sell Camel, Vantage, Now, Doral, Winston, Sterling, Magna, More, Century, Bright Rite and Salem cigarettes throughout the United States including the State of Ohio (collectively "RJR").

8. Defendant Brown & Williamson Tobacco Corporation is a Delaware corporation. Defendant Batus, Inc. is the parent of Brown & Williamson Tobacco Corporation and is a Wisconsin corporation. Defendant Batus Holdings, Inc. is the parent of Batus, Inc. and is a Delaware corporation. The principal place of business of Defendants Brown & Williamson Tobacco Corporation, Batus, Inc. and Batus Holdings, Inc. is 1500 Brown & Williamson Tower, Louisville, Kentucky. Defendants Brown & Williamson Tobacco Corporation, Batus, Inc. and Batus Holdings, Inc. manufacture, advertise, market

and sell Kool, Barclay, BelAir, Capri, Raleigh, Richland, Laredo, Eli Cutter and Viceroy cigarettes throughout the United States including the State of Ohio (collectively "Brown & Williamson"). In addition to manufacturing, marketing and selling cigarettes within the State of Ohio, Brown & Williamson conducts business as a wholesale distributor of cigarettes and other tobacco products within the State of Ohio. Brown & Williamson conducts business as a wholesale distributor of cigarettes and other tobacco products at 3443 Medina Road, Medina, Ohio 44256-3320.

9. Defendant British American Tobacco Co., Ltd. is a British corporation whose principal place of business is Millbank, Knowle Green, Staines, Middlesex, England TW181DY. Brown & Williamson Tobacco Corporation is or was a subsidiary or division of British American Tobacco Co., Ltd.

10. Defendant B.A.T. Industries P.L.C. (hereinafter "B.A.T. Industries") is a British corporation with its principal place of business at Windsor House, 50 Victoria St., London. Through a succession of intermediary corporations and holding companies, B.A.T. Industries P.L.C. is the shareholder of Brown & Williamson Tobacco Corporation. Through Brown & Williamson, B.A.T. Industries P.L.C. has placed cigarettes into the stream of commerce with expectation that substantial sales of cigarettes would be made in the United States. In addition, B.A.T. Industries P.L.C. conducted, or through its agents and/or co-conspirators conducted, critical research for Brown & Williamson Tobacco Corporation on the issue of smoking and health. Further, Brown & Williamson Tobacco

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Corporation is believed to have sent to England research conducted in the United States on the issue of smoking and health in an attempt to remove sensitive and inculpatory documents from United States jurisdiction, and these documents were subject to the control of B.A.T. Industries P.L.C. B.A.T. Industries P.L.C. has been involved in the conspiracy described herein and the actions of B.A.T. Industries P.L.C. has affected and caused harm throughout the United States including the State of Ohio.

11. Defendants Philip Morris, Inc., and its parent, Defendant Philip Morris Companies, Inc., are Virginia corporations whose principal places of business are located at 120 Park Avenue, New York, New York. Defendants Philip Morris, Inc. and Philip Morris Companies, Inc. manufacture, advertise, market and sell Philip Morris, Merit, Cambridge, Marlboro, Benson & Hedges, Virginia Slims, Alpine, Dunhill, English Ovals, Galaxy, Players, Saratoga and Parliament cigarettes throughout the United States including the State of Ohio ("Philip Morris").

12. Defendant Liggett & Myers, Inc., is a Delaware corporation whose principal place of business is located at Main and Fuller, Durham, North Carolina. Liggett & Myers, Inc., is a wholly-owned subsidiary of Defendant Liggett Group, Inc., a Delaware corporation whose principal place of business is located at 700 West Main Street, Durham, North Carolina. Defendants Liggett & Myers, Inc., and Liggett Group, Inc., are subsidiaries of Defendant Brooke Group, Ltd., a Delaware corporation, whose principal place of business is located at 300 North Duke Street,

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Durham, North Carolina. Defendants Liggett & Myers, Inc., Liggett Group, Inc., and Brooke Group, Ltd., manufacture, advertise, market and sell Chesterfield, Decade, L&M, Pyramid, Dorado, Eve, Stride, Generic and Lark cigarettes throughout the United States including the State of Ohio (collectively "Liggett & Myers").

13. Defendants Lorillard Tobacco Company, Inc., and Lorillard, Inc., and their parent, Defendant Loews Corporation ("Loews"), are Delaware corporations whose principal places of business are located at 1 Park Avenue, New York, New York. Defendants Lorillard Tobacco Company, Inc., Lorillard, Inc., and Loews manufacture, advertise, market and sell Old Gold, Kent, Triumph, Satin, Max, Spring, Newport and True cigarettes throughout the United States including the State of Ohio (collectively "Lorillard"). In addition, upon information and belief, Loews holds certain rights to a system that "is especially attractive in enriching the nicotine content of reconstituted tobacco."

14. Defendant United States Tobacco Company and its parent, Defendant UST, Inc., are Delaware corporations whose principal places of business are located at 100 West Putnam Avenue, Greenwich, Connecticut. United States Tobacco Company and UST, Inc. manufacture, advertise, market and sell Sano cigarettes throughout the United States including the State of Ohio ("U.S. Tobacco").

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15. The Defendants named in paragraphs 7-15, above are sometimes collectively referred to in this Complaint as the "Tobacco Companies."

16. Defendant, The Council for Tobacco Research -- U.S.A., Inc., successor in interest to the Defendant Tobacco Industry Research Committee ("TIRC") (collectively "CTR"), is a nonprofit corporation organized under the laws of the State of New York with its principal place of business at 900 3rd Avenue, New York, New York 10022. In furtherance of the conspiracy more fully described herein, the CTR, on behalf of the Tobacco Companies, has repeatedly disseminated false information to the public through the print and electronic media within the State of Ohio and the County of Cuyahoga.

17. Defendant Tobacco Institute, Inc. ("Tobacco Institute"), is a New York corporation, whose principal place of business is located at 1875 "I" Street, N.W., Suite 800, Washington, D.C. The Tobacco Institute conducted business within the State of Ohio through its Statutory Agent who was registered with the Ohio Secretary of State up to and including October 20, 1989. The Tobacco Institute operated as the public relations and lobbying arm of the Tobacco Companies and as such the Tobacco Institute was an agent, representative and/or employee of the Tobacco Companies. While engaged in the course of conduct alleged herein, the Tobacco Institute was acting within the course and scope of its agency or employment and was acting with the consent, permission, authorization and knowledge of the Tobacco Companies. All actions of

Tobacco Institute alleged herein were ratified and approved by the officers or managing agents of the Tobacco Companies. The Tobacco Companies, CTR and the Tobacco Institute are sometimes referred to herein collectively as "Defendants" and/or the "Tobacco Industry."

18. Each Defendant is sued individually as a primary violator and as an aider and abettor who rendered substantial assistance in the accomplishment of the acts and/or omissions alleged herein. In acting to aid and abet and substantially assist the commission of the fraud and wrongful conduct complained of herein, each Defendant acted with an awareness and knowledge of the fraud and wrongful conduct and realized that its conduct would substantially assist the accomplishment of that fraud and was aware of its overall contribution to the conspiracy, scheme and common course of wrongful conduct alleged herein, including, but not limited to, the manipulation of nicotine content in cigarettes and the misrepresentation, concealment and suppression of information regarding the addictive nature and properties of nicotine.

19. Each Defendant is also sued as a co-conspirator and the liability of each arises from the fact that each Defendant knowingly entered into an agreement with the other Defendants and other known and unknown third parties to pursue, and knowingly pursued, the common course of conduct to commit or participate in the commission of all or part of the unlawful acts, plans, schemes, transactions, and artifices to defraud alleged herein, including, but not limited to the manipulation of nicotine content in cigarettes and the misrepresentation, concealment and suppression

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of information regarding the addictive nature and properties of nicotine.

20. Defendant Novelart Manufacturing Company d/b/a A. Topicz & Sons ("Novelart"), located at 2121 Section Road, Cincinnati, Ohio 45237, is a wholesale distributor of cigarettes and other tobacco products who negligently sold the products of the Tobacco Companies to retailers for resale throughout the State of Ohio and is liable to Plaintiffs and members of the Plaintiff Class pursuant to the negligence, strict liability and warranty claims contained herein.

21. Defendant EBY-Brown Company ("EBY-Brown"), located at 1982 Commerce Circle, Springfield, Ohio 45504-2012, is a wholesale distributor of cigarettes and other tobacco products who negligently sold the products of the Tobacco Companies to retailers for resale throughout the State of Ohio and is liable to Plaintiffs and members of the Plaintiff Class pursuant to the negligence, strict liability and warranty claims contained herein.

22. The Kroger Co. ("Kroger") whose principal place of business is Cincinnati, Ohio, owns and operates and has owned and operated retail grocery stores throughout the State of Ohio. Kroger has negligently sold cigarettes manufactured by the Tobacco Companies to Plaintiffs and members of the Plaintiff Class, and is liable to the Plaintiffs and the Plaintiff Class pursuant to the negligence, strict liability and warranty claims contained herein.

23. Riser Foods Inc. ("Riser") is a Delaware company whose principal place of business is Bedford, Ohio and who owns and

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operates, has owned and operated, or is the successor in interest to retail grocery stores throughout the State of Ohio. Riser has negligently sold cigarettes manufactured by the Tobacco Companies to Plaintiffs and members of the Plaintiff Class pursuant to the negligence, strict liability and warranty claims contained herein. The wholesale and retail distributors set forth in paragraphs 21 through 24 herein are sometimes collectively referred to as the "Wholesale/Retail Defendants."

IV. CLASS ACTION ALLEGATIONS

24. Plaintiffs bring this class action on behalf of themselves and all others similarly situated, for the purpose of asserting the claims alleged in this Complaint on a common basis. Plaintiffs' proposed class is defined as: (a) All nicotine dependent persons who are residents and/or citizens of the State of Ohio who have purchased and smoked cigarettes manufactured by the Tobacco Companies; (b) the estates, representatives, and administrators of these nicotine dependent cigarette smokers; and, (c) the spouses, children, relatives and "significant others" of these nicotine dependent cigarette smokers as their heirs or survivors (the "Plaintiff Class").

25. For purposes of further defining the Plaintiff Class (paragraph 25, above), and the claims asserted by Plaintiffs and the Plaintiff Class in this Complaint, "nicotine dependent" is defined as:

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(a) all cigarette smokers who have been diagnosed by a medical practitioner as nicotine-dependent; and/or

(b) all regular cigarette smokers who were or have been advised by a medical practitioner that smoking has had or will have adverse health consequences who thereafter do not or have not quit smoking; and/or

(c) persons who are or have been nicotine dependent as that phrase is defined under the criteria set forth in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorder, Fourth Edition, 1994 ("DSM IV").

For purposes of the Class definition and the claims asserted by Plaintiffs and Plaintiff Class in this Complaint, the term "addictive" refers to the persistent and repetitive intake of psychoactive substances despite evidence of harm and a desire to quit; the terms dependent/dependence and addictive/addiction are used interchangeably.

26. Excluded from the Plaintiff Class are Defendants herein, any entity in which any of the Defendants has a controlling interest, any officers, directors or employees of any of the Defendants, and the legal representatives, heirs, successors, and assignees of any of the Defendants or their officers, directors or employees.

27. This action is brought and may properly be maintained as a class action pursuant to the provisions of Rule 23(B)(1)-(4) and, as appropriate, 23(B)(1), (B)(2) and/or (B)(3) of the Ohio Rules of Civil Procedure. This action satisfies the numerosity, common-

ality, typicality, adequacy and predominance and superiority requirement of those provisions.

28. Numerosity of the Class. Ohio Civil Rule 23(A)(1). The Plaintiff Class is so numerous that the individual joinder of all its members is impracticable. Currently, an estimated two million (2,000,000) adult Ohioans smoke cigarettes. In addition, thousands of adolescents begin smoking for the first time every day. Cigarettes contain nicotine. Nicotine is an addictive drug which causes most cigarette smokers to become dependent on cigarettes. Plaintiffs allege that Defendants knew and intended that users of the Tobacco Companies' products would become addicted to these products. Accordingly, Plaintiffs are informed and believe, and on that basis allege, that the Plaintiff Class includes millions of members. Class members may be informed of the pendency of this class action by published and broadcast notice and/or other methods proscribed by the Civil Rules.

29. Existence and Predominance of Common Questions of Law and Fact. Civil Rule 23(A) and 23(B)(3). Common questions of law and fact exist as to all members of the Plaintiff Class and predominate over any questions affecting only individual members of the Plaintiff Class. These common legal and factual questions arise from two central issues, which do not vary from Plaintiff Class member to Plaintiff Class member and which may be determined without reference to the individual circumstances of any particular Plaintiff Class member: (1) Defendants' course of conduct in manufacturing, selling and/or distributing cigarettes in Ohio; and

(2) the biochemical and psychoactive properties of nicotine. These common legal and factual questions include, but are not limited to, the following:

(a) Whether the Special Projects Division of the CTR was fraudulently established to hide medical research that linked tobacco and disease and established that nicotine was addictive;

(b) Whether nicotine is addictive;

(c) Whether and when Defendants knew that nicotine is addictive;

(d) Whether Defendants knew or should have known that the levels of nicotine in their cigarettes were addictive;

(e) Whether Defendants have manipulated the levels of nicotine in their cigarettes;

(f) Whether Defendants have manipulated the nicotine levels in their cigarettes for the purpose of causing and sustaining dependence on their products;

(g) Whether Defendants' course of conduct in denying that nicotine is addictive and manipulating the levels of nicotine in their cigarettes so as to addict consumers or sustain addiction constitutes fraud, deception, intentional misrepresentation and/or concealment of material facts;

(h) Whether Defendants' conduct constitutes negligent misrepresentation;

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(i) Whether Defendants' conduct constitutes negligence;

(j) Whether Defendants violated Ohio Revised Code ("ORC") §1345.02, ORC §1345.03 and/or ORC §4165.02;

(k) Whether Defendants breached express warranties;

(l) Whether Defendants breached the implied warranty of merchantability;

(m) Whether Defendants are liable for intentional infliction of emotional distress;

(n) Whether Defendants negligently designed their cigarettes in terms of nicotine content;

(o) Whether Defendants failed adequately to warn or notify consumers regarding the addictive nature of cigarettes;

(p) Whether the consistent presence of certain (fixed) levels of nicotine in Defendants' cigarettes and Defendants' course of conduct in marketing them constitute a manufacturing, design, and/or marketing defect for purposes of strict product liability;

(q) Whether Defendants are strictly liable in tort for selling a dangerously defective product;

(r) Whether the Plaintiff Class members are threatened with irreparable harm and whether they are entitled to injunctive and other equitable relief including restitution, and disgorgement and, if so, the nature of such relief;

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(s) Whether the Plaintiff Class members are entitled to medical monitoring at Defendants' expense;

(t) Whether the Plaintiff Class is entitled to compensatory damages, and, if so, the nature and extent of such damages;

(u) Whether Defendants are liable for punitive or exemplary damages, and, if so, how much is necessary and appropriate to punish them for their conduct, and deter others, and fulfill the other policies and purposes of punitive and exemplary damages;

(v) How any and all punitive and exemplary damages awarded to Plaintiffs should be equitably allocated among the Plaintiff Class;

(w) Whether all of the Defendants have acted in concert to defraud, misrepresent and deceive the American public; and

(x) Whether there has been a conspiracy to defraud the American public and the United States Government by the Tobacco Industry.

30. Typicality of Claims. Civil Rule 23(A)(3). Plaintiffs' claims are typical of the claims of the members of the Plaintiff Class, all of whom have purchased and smoked cigarettes manufactured by the Tobacco Companies and have become addicted to those products. Plaintiffs and all members of the Plaintiff Class have sustained and/or will continue to sustain damages and injuries and are facing irreparable harm arising out of Defendants' common

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course of fraudulent conduct designed to create and sustain addiction to and dependency on cigarettes.

31. Adequacy of Representation. Civil Rule 23(A)(4). Plaintiffs are adequate representatives of the Plaintiff Class because they are members of the Plaintiff Class and their interests do not conflict with the interests of the members of the Plaintiff Class they seek to represent. They have retained counsel competent and experienced in the prosecution of complex consumer fraud, mass tort, and products liability class actions, and they intend to prosecute this action vigorously for the benefit of the Plaintiff Class. The interests of the members of the Plaintiff Class will be fairly and adequately protected by Plaintiffs and their counsel.

32. Superiority. Civil Rule 23(B)(3). A class action is superior to other available methods for the fair and efficient adjudication of this litigation since individual litigation of Plaintiff Class members' claims is impracticable. Even if any Plaintiff Class members could afford individual litigation, the court system could not. It would be unduly burdensome to the courts in which individual litigation of the facts of millions of cases would proceed. Individual litigation further presents a potential for inconsistent or contradictory judgments. Individual litigation increases the delay and expense to all parties and the court system in resolving the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by

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a single court. Notice of the pendency and of any resolution of this Plaintiff Class action can be provided to Plaintiff Class members by publication and broadcast.

33. The various claims asserted in this action are additionally or alternatively certifiable under the provisions of Civil Rule 23(B)(1) and/or 23(B)(2) because:

(a) The prosecution of separate actions by the individual members of the Plaintiff Class would create a risk of inconsistent or varying adjudications with respect to individual Plaintiff Class members, thus establishing incompatible standards of conduct for Defendants;

(b) The prosecution of separate actions by individual Plaintiff Class members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of the other Plaintiff Class members not parties to such adjudications or would substantially impair or impede the ability of such non-party Plaintiff Class members to protect their interests; and

(c) Defendants have acted or refused to act on grounds generally applicable to the Plaintiff Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Plaintiff Class as a whole.

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V. FACTUAL ALLEGATIONS COMMON TO ALL COUNTS

A. The Nicotine in Cigarettes is Highly Addictive

34. The Tobacco Companies reap enormous profits from their manufacture and sale of cigarettes throughout the United States including the State of Ohio. The Tobacco Companies make, advertise and sell cigarettes despite their knowledge of the following facts: more than 10 million Americans have died as a result of smoking cigarettes; more than 400,000 Americans die every year as a result of smoking cigarettes; almost one death in every five is due to a smoking-related illness; the leading cause of preventable death in the United States today is smoking cigarettes; smoking causes cardiovascular disease and is responsible for approximately one third of all heart disease deaths; smoking causes almost all lung and throat cancers and is responsible for approximately one-tenth of all cancer deaths; smoking causes various pulmonary diseases, including emphysema; smoking causes stillbirths and neonatal deaths among the babies of mothers who smoke; and, cigarettes may contain any number of approximately 700 "additives," including a number of toxic and dangerous chemicals including nicotine. Congressman Henry A. Waxman (D.Calif.), Chairman, House Subcommittee on Health and the Environment stated recently "that cigarettes are the single most dangerous consumer product ever sold."

35. Despite the overwhelming weight of scientific evidence that smoking cigarettes poses serious health risks, and despite the gruesome statistical legacy being left by the Tobacco Industry,

Source: https://www.industrydocuments.ucsf.edu/docs/ybd0001

approximately 50 million Americans, including over 2 million Ohioans, continue to smoke cigarettes, including 3,000 new teenage smokers everyday. These innocent victims continue to smoke because they are addicted to or dependent upon cigarettes. More specifically, they are addicted to nicotine, the drug in tobacco that causes an addiction similar to that suffered by users of heroin and cocaine.

36. Cigarettes contain nicotine. Nicotine is an addictive substance and the use of cigarettes results in addiction to them. Nicotine causes compulsive use of cigarettes, despite knowledge that they are harmful, if not lethal; nicotine has a psychoactive (mood-altering) affect on the brain; and, nicotine invokes what is called "reinforcing behavior," causing continued use of the nicotine-containing products. Additionally, cigarette smokers suffer an inability to quit, notwithstanding a desire to do so, and those who do quit (or attempt to) endure withdrawal symptoms such as headaches, insomnia, depression, lack of concentration and anxiety.

37. The addictive power of nicotine is further illustrated by these statistical facts: at least two-thirds of adults who smoke say they wish they could quit; 17 million Americans try to quit smoking each year, but fewer than 1 out of 10 succeed; for every smoker who quits 9 try and fail; 8 out of 10 smokers say they wish they had never started smoking; after surgery for lung cancer, almost half of the smokers resumed smoking; among smokers who suffer heart attack, 38% resume smoking while they are still in the

hospital; even when a smoker has his or her larynx removed, 40% try smoking again; 70% of young people ages 12 to 18 who smoke say they believe they are already dependent on cigarettes; and 40% of high school seniors who smoke regularly have tried to quit and failed. According to David A. Kessler, M.D., Commissioner of the United States Food and Drug Administration, "once they have started regularly, most smokers are in effect deprived of the choice to stop smoking....Seventeen million Americans try to quit smoking each year. But, more than fifteen million are unable to exercise that choice because they cannot break their addiction to cigarettes."

38. The 1988 Surgeon General's Report, "The Health Consequences of Smoking: Nicotine Addiction" concluded: (1) "Cigarettes and other forms of tobacco are addicting"; (2) "Nicotine is the drug in tobacco that causes addiction"; and (3) "The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine." Nicotine in cigarettes is now recognized as an addictive substance by such major medical organizations as the Office of U.S. Surgeon General, the World Health Organization, the American Medical Association, the American Psychiatric Association, the American Psychological Association, the American Society of Addiction Medicine, the American Public Health Association, and the Medical Research Counsel in the United Kingdom. The National Institute on Drug Abuse recently called

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cigarette smoking the most common example of drug dependence in the United States.

39. In its August 1995 Report the U.S. Food and Drug Administration, Department of Health and Human Services ("U.S.F.D.A. 1995 Report"), concluded that:

> The vast majority of smokers and many smokeless tobacco consumers, because they are addicted to nicotine, use cigarettes and smokeless tobacco to satisfy nicotine dependence. Many of these consumers also use these products to affect mood and to control weight. (Emphasis supplied).

40. Despite the recognition of nicotine's addictive properties by these and other organizations, the Tobacco Companies continue to misinform the American public. Although it now appears the Tobacco Companies have known for decades, on the basis of their own long-concealed research and testing, that nicotine is addictive, the Tobacco Companies have denied, and continue to deny, that nicotine is addictive.

B. The Tobacco Industry Conspiracy: Deceiving The Public To Increase Profits

1. The Tobacco Industry Conspiracy Commences With The Creation Of The Tobacco Industry Research Committee ("TIRC")

41. The industry conspiracy began as early as the 1950's, when cigarette manufacturers were confronted with the publication of several scientific studies which sounded grave warnings on the health hazards of cigarettes. One of the first of these studies

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was published in 1952 by Dr. Richard Doll, a British researcher. Dr. Doll, in a statistical analysis, found that lung cancer was more common among people who smoked and that the risk of lung cancer was directly proportional to the number of cigarettes a person smoked.

42. A report published in December, 1953 by Dr. Ernst L. Wynder of the Sloan-Kettering Institute disclosed to the scientific community and to the Tobacco Companies, a definitive link between smoking and cancer. In these tests, researchers painted, condensed cigarette smoke onto the backs of mice. Malignant tumors grew in 44% of the mice. While previous statistical and epidemiologic studies indicated a relationship between smoking and cancer, Dr. Wynder's study demonstrated a direct biological link between smoking and cancer. (Although Defendants have sought to discredit the Wynder findings, recently disclosed documents include a 1962 letter from Lorillard to Dr. Wynder, regarding his work establishing smoking to be a carcinogen and the principal cause of lung cancer, and stating that Lorillard "considered [Dr. Wynder's] work above reproach, as usual.")

43. The Doll and Wynder studies generated widespread public concern about the health hazards of cigarettes. The widespread reporting of these studies caused what cigarette company officials later called the "Big Scare."

44. Confronted with this evidence, the presidents of the leading tobacco companies met at an extraordinary gathering in the

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Plaza Hotel in New York City in December of 1953. The presidents acknowledged the seriousness of the Doll and Wynder studies but viewed these studies and the underlying scientific evidence entirely in terms of a public relations problem rather than a public health concern. In fact, the public relations firm of Hill & Knowlton, who coordinated this meeting, summarized in an internal memorandum the key issues discussed at the meeting:

> (a) the conclusion that the medical and public relations problems confronting the Tobacco Companies were "extremely serious and worthy of drastic action."
>
> (b) the conclusion that the serious nature of this problem was underscored by the fact that "the salesmen in the industry are frantically alarmed and that the decline in tobacco stocks on the stock exchange market has caused grave concern."

Together, all the leading manufacturers, except Liggett & Myers, agreed to launch a concerted public relations strategy to promote the positive nature of cigarettes. Even though at that time, Liggett & Myers chose to confront these issues by "[ignoring] the whole controversy", Liggett & Myers later became actively involved in the overall conspiracy to addict Plaintiffs and the members of the Plaintiff Class through the manipulation of nicotine levels in cigarettes.

45. Thus, the Tobacco Industry Research Committee (previously designated the "TIRC") was conceived and born. Five of the Big Six cigarette manufacturers, i.e., American Tobacco, Brown & Williamson, Lorillard, Philip Morris, RJR and U.S. Tobacco were

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original members. Liggett & Myers did not join until 1964, the same year that the Surgeon General issued its first report on smoking and health and concluded that cigarette smoking was a cause of lung cancer. Also in 1964, TIRC changed its named to the Council for Tobacco Research (previously designated the "CTR").

46. The Tobacco Industry announced the formation of the TIRC on January 4, 1954, with a newspaper announcement placed in virtually every city with a population of 50,000 or more, reaching a total circulation of more than 43 million Americans. The announcement, which appeared in both the Cleveland Press and the Cleveland Plain Dealer, was captioned "A Frank Statement to Cigarette Smokers" and was run under the auspices of the TIRC with, inter alia, five of the Big Six manufacturers listed by name.

47. In this announcement, the participating Tobacco Companies expressly represented to the public, including residents and citizens of Ohio, that they acknowledged and accepted their "special responsibility" to the public concerning the health hazards associated with cigarette smoking, and promised to learn the facts about smoking and health. This advertisement, provided in part:

> RECENT REPORTS on experiments with mice have given wide publicity to a theory that cigarette smoking is in some way linked with lung cancer in human beings.
>
> Although conducted by doctors of professional standing, these experiments are not regarded as conclusive in the field of cancer research. However, we do not believe that any serious medical research, even though its results are

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inconclusive should be disregarded or lightly dismissed.

* * *

We accept an interest in people's health as a basic responsibility, paramount to every other consideration in our business.

We believe the products we make are not injurious to health.

We always have and always will cooperate closely with those whose task it is to safeguard the public health.

* * *

Regardless of the record of the past, the fact that cigarette smoking today should even be suspected as a cause of a serious disease is a matter of deep concern to us.

Many people have asked us what, we are doing to meet the public's concern aroused by the most recent reports. Here is the answer:

1. We are pledging aid and assistance to the research effort into all phases of tobacco use and health. This joint financial aid will of course be in addition to what is already being contributed by individual companies.

2. For this purpose we are establishing a joint industry group consisting initially of the undersigned. This group will be known as TOBACCO INDUSTRY RESEARCH COMMITTEE.

3. In charge of the research activities of the Committee will be a scientist of impeccable integrity and national repute. In addition there will be an Advisory Board of scientists disinterested in the cigarette industry. A group of distinguished men from medicine, science, and education will be invited to serve on this Board. These scientists will advise the Committee on its research activities.

This statement is being issued because we believe the people are entitled to know where

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> we stand on this matter and what we intend to do about it. (Emphasis supplied).

In other words, the participating Tobacco Companies promised to sponsor independent research on the subject, claiming they would make health a basic responsibility paramount to any other consideration in their business. The participating Tobacco Companies also promised to cooperate closely with public health officials. At the time these promises were made, the Tobacco Companies had no intent to honor their promises. In fact, these promises so publicly and dramatically made to the public have been repeatedly breached by the Tobacco Industry.

48. After lulling the public into a false sense of security concerning smoking and health, the TIRC continued to act as a front for the interests of the Tobacco Industry. Despite the initial public statements and posturing, and the repeated assertions over the years that the Tobacco Industry was committed to full disclosure and vitally concerned with public health, the TIRC failed to make the public health of cigarette smokers a concern. Rather the TIRC, at the direction of the Tobacco Companies, acted to protect the Tobacco Industry's profits and failed to protect the public health. Beginning with the January 4, 1954 nationwide newspaper advertisement entitled "A Frank Statement To Cigarette Smokers," a coordinated, industry-wide strategy was designed to actively mislead, confuse and conceal from the public the true dangers associated with smoking cigarettes. Rather than work for the good of the public health and sponsor independent research, as it had

promised, the Tobacco Companies, acting through the TIRC/CTR, concealed, undermined and distorted information coming from the scientific and medical community.

2. **The Tobacco Industry Conspiracy: From Its Inception Through Today**

49. In 1946, Tobacco Company chemists themselves reported concern for the health of smokers. A 1946 letter from a Lorillard chemist to its manufacturing committee states that "Certain scientists and medical authorities have claimed for many years that the use of tobacco contributes to cancer development in susceptible people. Just enough evidence has been presented to justify the possibility of such a presumption."

50. The health claim advertising campaigns by the Tobacco Companies were patently false, misleading, deceptive and/or fraudulent. These campaigns were disseminated nationally in popular magazines, press, radio and television and were calculated to induce non-smokers to commence smoking and to induce smokers to continue in their addiction to their harm and injury and to the damage of the Plaintiffs and members of the Plaintiff Class.

51. In the 1930s, in response to what industry spokesmen referred to as "the health scare," the Tobacco Companies made express claims and warranties as to the healthiness of their products with reckless disregard to the falsity of their claims and the consequential adverse impact on consumers. Examples of these health warranties include the following: Old Gold - "Not a cough

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Source: https://www.industrydocuments.ucsf.edu/docs/ytxl0001

in a Carload;" Camel - "Not a single case of throat irritation due to smoking Camels;" Philip Morris - "The Throat-tested cigarette."

52. In the New York State Journal of Medicine, Chesterfield ads began running in 1933. They often carried claims such as, "Just as pure as the water you drink and practically untouched by human hands."

53. In 1942, Brown and Williamson claimed that Kools would keep the head clear and/or give extra protection against colds.

54. For 15 years, Philip Morris used various claims, including one it ran in the New York State Medical Journal in 1935 touting studies that purportedly showed Philip Morris cigarettes were less irritating. An ad by the company in a 1943 issue of the National Medical Journal read: "'Don't smoke' is advice hard for patients to swallow. May we suggest instead 'Smoke Philip Morris!' Tests showed three out of every four cases of smokers' cough cleared on changing to Philip Morris. Why not observe the results for yourself?" An ad by the company in JAMA in 1949 stated: "Why many leading nose and throat specialists suggest. 'Change to Philip Morris'...."

55. During the 1950s the Tobacco Companies employed yet another method of description in manufacturing and advertising to boost sales to counter the "health scare." The Tobacco Companies manufactured filtered cigarettes that were advertised with explicit and/or implicit warranties of tar/nicotine content and health claims. The Tobacco Companies' health claims and claims as to the

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effectiveness of the filters in removing tar and nicotine were knowingly deceptive when made, and/or were made with reckless disregard for the health risks to the cigarette smokers.

56. A publication called Tobacco and Health (later Tobacco and Health Research) was created by the Tobacco Industry and was used by them to disseminate false information and create confusion over the causal connection between cigarette smoking and disease. It was distributed to the press, doctors, and health officials. The "Criteria for Selection" of articles for publication included an example of "a report in which smoking-associated diseases are questioned."

57. The deceptions and misrepresentation made by the Tobacco Industry in the 1954 "Frank Statement to Cigarette Smokers" have, over the years, been repeatedly renewed by the Tobacco Industry. For example, in furtherance of the conspiracy, RJR Chairman Bowman Gray told Congress in 1964: "If it is proven that cigarettes are harmful, we want to do something about it regardless of what somebody else tells us to do. And we would do our level best. It's only human."

58. The January 15, 1968 issue of True Magazine contained an article written by Stanley Frank called "To Smoke or Not to Smoke -- That is Still the Question." The article dismissed the evidence against smoking as "inconclusive and inaccurate" and claimed that "[s]tatistics alone link cigarettes with lung cancer -- it is not accepted as scientific proof of the cause and effect." A few

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months later, a similar but shorter article appeared in the National Enquirer entitled "Cigarette Cancer Link is Bunk" written by "Charles Golden" (a fictitious name commonly used by the Enquirer.) The real author was Stanley Frank. Two million reprints of the True Magazine article were distributed to physicians, scientists, journalists, government officials, and other opinion leaders with a small card which stated. "As a leader in your profession and community, you will be interested in reading this story from the January issue of True Magazine about one of today's controversial issues." The cost for this was paid by Brown and Williamson, Philip Morris and R.J. Reynolds. It was subsequently disclosed that Stanley Frank had been paid $500 to write the article by Joseph Field, a public relations professor working for Brown and Williamson. Brown and Williamson reimbursed Field for that amount.

59. In 1970, in furtherance of the conspiracy, the Tobacco Institute ran a follow-up announcement captioned "A Statement About Tobacco and Health" which stated:

> a. "We recognize that we have a special responsibility to the public -- to help scientists determine the facts about tobacco and health, and about certain diseases that have been associated with tobacco use."
>
> b. "We accepted this responsibility in 1954 by establishing the Tobacco Industry Research Committee which provides research grants to independent scientists. We pledge continued support of this program of research until all the facts are known."
>
> c. "Scientific advisors inform us that until much more is known about such diseases

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as lung cancer, medical science probably will not be able to determine whether tobacco or any other single factor plays a causative role -- or whether such a role might be direct or indirect, incidental or important."

d. "We shall continue all possible efforts to bring the facts to light." (Emphasis supplied).

60. Also, in 1970, the Tobacco Institute ran yet another announcement captioned "The question about smoking and health is still a question." In this announcement, the Tobacco Institute stated:

a. "[A] major portion of this scientific inquiry has been financed by the people who know the most about cigarettes and have a great desire to learn the truth ... the tobacco industry."

b. "[T]he industry has committed itself to the task in the most objective and scientific way possible."

c. "In the interest of absolute objectivity, the tobacco industry has supported totally independent research efforts with completely nonrestrictive funding."

d. "Completely autonomous, CTR's research is directed by a board of ten scientists and physicians... This board has full authority and responsibility for policy, development and direction of the research effort."

e. "The findings are not secret."

f. "From the beginning, the tobacco industry has believed that the American people deserve objective scientific answers.

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61. Again, in 1970, the Tobacco Institute stated "The Tobacco Institute believes that the American public is entitled to

complete, authenticated information about cigarette smoking and health." The Tobacco Institute further stated that "The tobacco industry recognizes and accepts a responsibility to promote the progress of independent scientific research in the field of tobacco and health."

62. These statements, as made public to Ohio consumers, including Plaintiffs and members of the Plaintiff Class, were published on behalf of the Tobacco Industry in furtherance of the conspiracy and with the malicious intent (1) to misrepresent facts known or which reasonably should have been known by the Tobacco Industry and/or (2) to withhold material facts which were known or which reasonably should have been known by the Tobacco Industry; these misrepresentations and/or material omissions were made by the Tobacco Industry with the knowledge and intent that such misrepresentations and omissions would be relied upon by Plaintiffs and members of the Plaintiff Class; and these misrepresentations and omissions were in fact relied upon by Plaintiffs and members of the Plaintiff Class.

63. In direct contrast to what the Tobacco Industry was telling the public, a memo from Tobacco Institute vice president Fred Panzer to president Horace Kornegay dated May 1, 1972, acknowledged that the industry had employed a single strategy for nearly 20 years to defend itself on three major fronts: litigation, politics, and public opinion. This strategy consisted of "creating doubt about the health charge without actually denying it -- advocating the public's right to smoke without actually urging

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Source: https://www.industrydocuments.ucsf.edu/docs/fyd0001

them to take up the practice -- encouraging objective scientific research as the only way to resolve the question of health hazard." Panzer said this strategy had been successful on the litigation front and had "helped make possible an orderly retreat" on the political front, but that the situation had deteriorated on the public opinion front. To remedy the public opinion problem, he proposed that the Tobacco Industry supply the public with "ready made credible alternatives" to the prevalent view that smoking causes cancer, such as generic and environmental explanations for smoking-related diseases.

64. On April 14, 1994, the chief executives of the Tobacco Companies testified under oath before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives, chaired by Congressman Waxman. These executives knowingly made material misrepresentations and/or omissions to the Subcommittee about smoking, health and addiction, and in particular, stated that nicotine is not addictive. These statements were made with the knowledge that they would be communicated to Ohio consumers. This testimony to the Subcommittee included the following:

a. Andrew Tisch, then CEO of Lorillard, asserted that smoking does not cause cancer. "We have looked at the data and the data that we have been able to see has all been statistical data that has not convinced me that smoking causes death."

b. Philip Morris President and CEO William I. Campbell said that:

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(1) "Philip Morris does not manipulate nor independently control the level of nicotine in our products."

(2) "Cigarette smoking is not addictive."

(3) "Philip Morris research does not establish that smoking is addictive."

c. R.J. Reynolds CEO James W. Johnson said that "smoking is no more addictive than coffee, tea or Twinkies."

65. An announcement placed by Philip Morris in newspapers across the county in April 1994, affirmatively represented that Philip Morris does not "manipulate" nicotine levels in its cigarettes, and that "Philip Morris does not believe that cigarette smoking is addictive."

66. RJR placed a similar announcement in newspapers across the United States in 1994 stating that "we do not increase the level of nicotine in any of our products in order to addict smokers. Instead of increasing the nicotine levels in our products, we have in fact worked hard to decrease tar and nicotine...." RJR's announcement then touted its use of "various techniques that help us reduce the tar [and consequently the nicotine] yields of our products."

67. These statements mislead the consuming public because, as alleged above, Philip Morris and RJR use various sophisticated techniques to increase the nicotine content in their cigarettes and thus, the actual nicotine delivery to the smokers.

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http://legacy.library.ucsf.edu/tid/ekk07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/dzyl0001

68. The recent disclosures of the sworn testimony of a former research chief for Brown & Williamson Tobacco Corporation, Dr. Jeffrey S. Wigand, and former Philip Morris scientists, Jerome Rivers, Dr. Ian L. Uydess and Dr. William Frone, directly contradict the testimony of the Tobacco Companies regarding addiction, as well as the Tobacco Industry's denial of nicotine manipulation.

3. In Furtherance Of The Conspiracy The Tobacco Industry Suppressed The "Safer" Cigarette

69. Even though the Tobacco Companies could have designed and manufactured a safer cigarette, the Tobacco Companies have failed and refused to do so. The need for a "safer" tobacco product results from the harmful chemical compounds occurring in cigarettes and/or formed as a result of burning. These compounds include carbon monoxide, nicotine, nickel, carbon dioxide, benzene, hydrazine, formaldehyde, Polonium-210, ammonia, nicotine sulfate, Freon II, hydrogen cyanide and certain liver toxins known collectively as furans. More than forty (40) known carcinogens are found in cigarette tobacco. The Tobacco Companies artificially add chemicals and flavorings to their products that increase toxicity and/or carcinogenicity.

70. At Liggett & Myers, Dr. James Mold conducted tests to divide the components of cigarette smoke into separate components in order to interrupt the process that produces carcinogens through the use of a catalyst. Liggett & Myers researchers were able to produce a so-called "safer" cigarette, designated as the "XA Project" that eliminated the carcinogenic activity on mouse skin.

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However, Liggett & Myers did not want to be identified publicly as the source of the research behind this non-carcinogenic "safer" cigarette.

71. Liggett & Myers instructed its researchers that any meetings held that pertained to the "safer" cigarette project were to be attended by a lawyer and that all reports, notes or memoranda should go to the Liggett & Myers legal department. The "safer" cigarette was never marketed.

72. Liggett & Myers abandoned its XA Project for two apparent reasons. One was that Liggett & Myers feared that the marketing of a "safer" cigarette would be, in essence, a concession that its -- and the Tobacco Industry's other cigarettes were not safe. Second, industry leader Philip Morris threatened to retaliate against Liggett & Myers if it broke ranks with the ongoing Tobacco Industry conspiracy.

73. Dr. Mold, who was assistant director of research at Liggett & Myers during the development of the "safer" cigarette, has provided the following overview of the XA Project and its abandonment:

a. Dr. Mold stated that the XA project produced a safer cigarette. He stated, "We produced a cigarette which was, we felt, commercially acceptable as established by some consumer tests, which eliminated carcinogenic activity...."

b. Dr. Mold stated that after 1975, all meetings on the project were attended by lawyers. Lawyers collected notes after all meetings. All documents were directed to the

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law department to cloak the documents with the attorney-client privilege. He stated, "Whenever any problem came up on the project, the Legal Department would pounce upon that in an attempt to kill the project, and this happened time and time again."

c. Dr. Mold was asked why Liggett & Myers didn't market a safer cigarette. He stated,

> "Well, I can't give you, you know, a positive statement because I wasn't in the management circles that made the decision, but I certainly had a pretty fair idea why...(T)hey felt that such a cigarette, if put on the market, would seriously indict them for having sold other types of cigarettes that didn't contain this, for example...(a)t a meeting we held in...New Jersey at the Grand Met headquarters...at which the various legal people involved and the management people involved and myself were present. At one point, Mr. Dey...who at that time, and I guess still is the president of Liggett Tobacco, made the statement that he was told by someone in the Philip Morris Company that if we tried to market such a product that they would clobber us."

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74. A memorandum authored by an attorney at the firm of Shook, Hardy & Bacon, long-time lawyers for the Tobacco Industry, confirmed the existence of the conspiratorial nature of the Tobacco Industry's position regarding the production and sales of a "safer" cigarette.

75. The 1987 memorandum was written in the context of the marketing by RJR of a smokeless cigarette, Premier, that heated rather than burned tobacco. The Shook, Hardy attorney wrote that the smokeless cigarette could "have significant effects on the

tobacco industry's joint defense efforts" and "(t)he industry position has always been that there is no alternative design for a cigarette as we know them." The attorney also noted that, "Unfortunately, the Reynolds announcement...seriously undercuts this component of industry's defense."

C. Despite Its Knowledge That Nicotine Is Addictive, The Tobacco Industry Falsely Claims That Nicotine Is Not Addictive

76. By no later than the early 1960s and perhaps as early as the 1940's Defendants were fully aware, based on their own scientific research, that nicotine is an addictive substance and that regular cigarette smoking results in nicotine dependence. For example, an internal Philip Morris report from 1971 describes the difficulties a smoker has in stopping smoking once he or she is addicted to nicotine: "Even after eight months quitters were apt to report having neurotic symptoms, such as feeling depressed, being restless and tense, being ill-tempered, having a loss of energy, being apt to doze off, etc. They were further troubled by constipation and weight gains...."

77. An internal report written in 1973 by William L. Dunn, Jr., a senior scientist with Philip Morris, provides a more startling picture:

> The primary incentive to cigarette smoking is the immediate salutatory affect of inhaled smoke upon body function....As with eating and copulating, so it is with smoking. The physiological effects serve as the primary incentive; all other incentives are secondary ....Without nicotine, the argument goes, there

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would be no smoking. Some strong evidence can be marshalled to this argument:

1) No one has ever become a cigarette smoker by smoking cigarettes without nicotine.

2) Most of the physiological responses to inhaled smoke have been shown to be nicotine-related. (Emphasis supplied).

78. Another internal Philip Morris document, this one from 1981, acknowledges that

> Nicotine is a powerful pharmacological agent with multiple sites of action and may be the most important component of cigarette smoke. Nicotine and an understanding of its properties are important to the continued well being of our cigarette business since this "alkaloid has been cited often as the reason for smoking" and theories have been advanced for "nicotine titration" by the smoker. Nicotine is known to have affects on the central nervous system as well as influencing memory, learning, pain perception, response to stress and level of arousal. (Emphasis supplied).

79. Additional documents, which are similarly replete with evidence of the Tobacco Industry's knowledge of the addictive nature of nicotine, further demonstrate the Tobacco Industry's wanton and reckless disregard of this knowledge:

(a) In 1962, Sir Charles Ellis, scientific advisor to the board of directors of British American Tobacco Company ("BATCO"), Brown & Williamson's parent company, stated at a meeting of BATCO's worldwide subsidiaries, that "smoking is a habit of addiction" and that "[n]icotine is not only a very fine drug, but the technique of administration by smoking has considerable

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psychological advantages...." He subsequently described Brown & Williamson as being "in the nicotine rather than the tobacco industry."

(b) A research report from 1963 commissioned by Brown & Williamson states that when a chronic smoker is denied nicotine: "A body left in this unbalanced state craves for renewed drug intake in order to restore the physiological equilibrium. This unconscious desire explains the addiction of the individual to nicotine." No information from that research has ever been voluntarily disclosed to the public; in particular, it was not shared with the Committee that was preparing the first United States Surgeon General's report and hence was not reflected in that report.

(c) Addison Yoaman, General Counsel at Brown & Williamson, summarized his view about nicotine in a 1963 internal memorandum:

> Moreover, nicotine is addictive. We are, then, in the business of selling nicotine, an addictive drug....

(d) Internal reports prepared by Philip Morris in 1972 and the Philip Morris U.S.A. Research Center in March 1978 demonstrate Philip Morris' understanding of the role of nicotine in tobacco use: "We think that most smokers can be considered nicotine seekers, for the pharmacological effect of nicotine is one of the rewards that come from smoking. When the smoker quits, he

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forgoes his accustomed nicotine. The change is very noticeable, he misses the reward, and so he returns to smoking."

(e) In a 1972 document entitled "RJR Confidential Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein," an RJR executive wrote:

> In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized, and stylized segment of the pharmaceutical industry. Tobacco products uniquely contain and deliver nicotine, a potent drug with a variety of physiological effects.

80. Documents from a BATCO study called Project Hippo, uncovered only in May 1994, show that as far back as 1961, this cigarette company was actively studying the physiological and pharmacological effects of nicotine. In furtherance of the Tobacco Industry conspiracy, Project Hippo reports were circulated to other Tobacco Companies and to the TIRC, demonstrating both that the Tobacco Industry's nicotine research was shared and that the individual members of the Tobacco Industry were acting in concert to achieve a single goal -- the addiction of millions of Americans and therefore Ohioans to obtain as much profit as could be reaped from this senseless addiction. BATCO sent the reports to officials at Brown & Williamson and RJR, and circulated a copy to TIRC with a request that TIRC "consider whether it would help the U.S. industry for these reports to be passed on to the Surgeon General's Committee." Ultimately, these reports were withheld from the Surgeon General's Committee to the detriment of Plaintiffs and members of the Plaintiff Class.

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81. Similarly, an RJR-MacDonald Marketing Summary Report from 1983 concluded that the primary reason people smoke "is probably the physiological satisfaction provided by the nicotine level of the product."

82. To this day, the Tobacco Companies, acting in concert with each other and the Tobacco Industry, have actively concealed from public health officials, the public and therefore Plaintiffs and members of the Plaintiff Class their extensive knowledge of the addictive properties of nicotine and its critical role in smoking while continuing to publicly proclaim that nicotine is not addictive and that cigarettes are not harmful to health.

83. As recently as December 1995, the Wall Street Journal reported on an internal Philip Morris draft document analyzing the competitive market for nicotine products for the years 1990-1992. The report describes the importance of nicotine: "Different people smoke for different reasons. But the primary reason is to deliver nicotine into their bodies." It is a physiologically active, nitrogen containing substance. Similar organic chemicals include nicotine, quinine, cocaine, atropine and morphine. While each of these substances can be used to affect human physiology, nicotine has a particularly broad range of influence. During the smoking act, nicotine is inhaled into the lungs in smoke, enters the bloodstream and travels to the brain in about eight to ten seconds."

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84. Recently disclosed handwritten notes dated 1965 from Ronald A. Tamol, who until 1993 was Philip Morris' Director of Research and Brand Development, refer to "minimum nicotine ... to keep the normal smoker hooked."

85. Patent filings by the Tobacco Companies further reveal their knowledge of the addictive quality of nicotine. In a 1971 patent filing, Philip Morris talks about maintaining the "nicotine content at a sufficiently high level to provide the desired physiological activity." Years of numerous patent filings by the Tobacco Companies underscore the industry's knowledge that nicotine is addictive.

86. Despite their knowledge that as a result of nicotine, cigarette smoking is extremely addictive, the Tobacco Companies continue to deny that smoking is addictive. Through their sworn testimony to Congress, their individual advertising and public relations campaigns, and collectively through the Tobacco Institute, the Tobacco Companies have successfully promoted and sold cigarettes by concealing and misrepresenting their highly addictive nature.

87. However, at the same time that the Tobacco Companies were publicly denying to Congress and the American people, including Plaintiffs and members of the Plaintiff Class, the addictive nature of nicotine, the U.S. Food and Drug Administration was investigating nicotine addiction from cigarettes. The FDA concluded:

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> The Food and Drug Administration has conducted an extensive investigation and has engaged in comprehensive analysis regarding the agency's jurisdiction over nicotine-containing cigarettes and smokeless tobacco products.
>
> . . .
>
> The Agency has obtained evidence concerning the knowledge of cigarette and smokeless tobacco product manufacturers about the pharmacological and addictive effects of nicotine in cigarettes and smokeless tobacco, and their manipulation of nicotine delivery to satisfy users' physiological need for nicotine, from the major manufacturers of these products and from CTR.

(U.S.F.D.A. 1995 Report).

88. On February 25, 1994, David A. Kessler, M.D., Commissioner of the FDA, sent a letter to Scott D. Bailin, Esq., Chairman of the Coalition on Smoking and Health asserting:

> Evidence brought to our attention is accumulating that suggests that cigarette manufacturers may intend that their products contain nicotine to satisfy an addiction on the part of some of their customers. The possible inference that cigarette vendors intend cigarettes to achieve drug effects in some smokers is based on mounting evidence we have received that (1) the nicotine ingredient in cigarettes is a powerfully addictive agent and (2) cigarette vendors control the levels of nicotine that satisfy this addiction.

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89. In response to Kessler's letter, on March 15, 1994, in a letter to The New York Times, James W. Johnston, Chairman and Chief Executive Officer of RJR, continued to assert that nicotine was not addictive. Johnston based his assertion upon the success rate of American adults who had quit smoking.

http://legacy.library.ucsf.edu/tid/plr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/

90. On March 25, 1994, David Kessler testified before the Waxman Subcommittee that "the cigarette industry has attempted to frame the debate on smoking as the right of each American to choose. The question we must ask is where smokers really have the choice." Dr. Kessler stated:

> a. "Accumulating evidence suggests that cigarette manufacturers may intend this result -- that they may be controlling the levels of nicotine in their products in a manner that creates and sustains an addiction in the vast majority of smokers."
>
> b. "We have information strongly suggesting that the amount of nicotine in a cigarette is there by design."
>
> c. "[T]he public thinks of cigarettes as simply blended tobacco rolled in paper. But they are much more than that. Some of today's cigarettes may, in fact, qualify as high technology nicotine delivery systems that deliver nicotine in precisely calculated quantities -- quantities that are more than sufficient to create and sustain addition in the vast majority of individuals who smoke regularly."
>
> d. "[T]he history of the tobacco industry is a story of how a product that may at one time have been a simple agricultural commodity appears to have become a nicotine delivery system."
>
> e. "[T]he cigarette industry has developed enormously sophisticated methods for manipulating nicotine levels in cigarettes."
>
> f. "In many cigarettes today, the amount of nicotine present is a result of choice, not change. [S]ince the technology apparently exists to reduce nicotine in cigarettes to insignificant levels, why, one is led to ask, does the industry keep nicotine in cigarettes at all?"

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Source: https://www.industrydocuments.ucsf.edu/docs/jxx0003

91. On June 21, 1994, Dr. Kessler told the Waxman Subcommittee that FDA investigators had discovered that Brown & Williamson had developed a high nicotine tobacco plant, which the company called Y-1. This discovery followed Brown & Williamson's flat denial to the FDA on May 2, 1994, that it had engaged in "any breeding of tobacco for high or low nicotine levels."

92. When four FDA investigators visited the Brown & Williamson plant in Macon, Georgia on May 3, 1994, Brown & Williamson officials denied that the company was involved in breeding tobacco for specific nicotine levels.

93. In fact, in a decade-long project, Brown & Williamson secretly developed a generically engineered tobacco plant with a nicotine content more than twice the average found naturally in flue-cured tobacco. Brown & Williamson took out a Brazilian patent for the new plant, which was printed in Portuguese. Brown & Williamson and a Brazilian sister company. Souza Cruz Overseas, grow Y-1 in Brazil and shipped it to the United States where it was used in five Brown & Williamson cigarette brands sold in Ohio, including three labeled "light." When the company's deception was uncovered, company officials stated that nearly four million pounds of Y-1 were stored in company warehouses in the United States.

94. As part of its cover-up, Brown & Williamson even went so far as to instruct the DNA Plant Technology Corporation of Oakland, California, which had developed Y-1, to tell FDA investigators that Y-1 had "never [been] commercialized." Only after the FDA

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Source: https://www.industrydocuments.ucsf.edu/docs/dyl0001

discovered two United States Customs Service invoices indicating that "more than a million pounds" of Y-1 tobacco had been shipped to Brown & Williamson on September 21, 1992, did the company admit that it had developed the high-nicotine tobacco.

95. The public, including Plaintiffs and members of the Plaintiff Class, is only now learning of the measures taken by the Tobacco Industry to misrepresent, omit and conceal the truth about nicotine. On March 31, 1994, Congressman Waxman released a copy of a previously secret Philip Morris-funded research study substantiating the addictive nature of nicotine. Philip Morris scientists, upon conducting tests, found strong evidence concerning the addictive nature of nicotine, which suggested that further testing should be done. The experiment used in the study -- self-administration by rats -- is one of the primary tests used by the U.S. Food and Drug Administration, the U.S. Drug Enforcement Agency and the World Health Organization to determine whether a drug is addictive. The research was submitted in 1983 to the scientific journal Psychopharmacology and was accepted for publication. Prior to publication, the journal was notified by the scientist that the article was being withdrawn citing "factors beyond my control." The scientist subsequently left Philip Morris and in 1986 resubmitted a revised version of the article to the journal. After the article was again accepted for publication, the scientist was again forced to withdraw it by Philip Morris.

96. Had the Tobacco Companies disclosed their knowledge of the addictive nature of nicotine, the public, including Plaintiffs

and members of the Plaintiff Class would have years ago become aware of the fact of the addictiveness of nicotine and the scientific and medical community would have years ago had access to critical secrets of the Tobacco Industry on the subject, which would have resulted in a more rapid popular determination and consensus on the subject. The Tobacco Industry engaged in an ongoing conspiracy to actively misrepresent, omit and conceal the truth about nicotine in order to sustain the addictions of existing cigarette smokers and to "hook" thousands of new smokers every day, including Plaintiffs and members of the Plaintiff Class, so that the Tobacco Companies could continue to profit at the expense of the lives and health of the consuming public. In fact, according to an April 31, 1994 article in the Houston Chronicle, approximately 25.4 billion packs of cigarettes are sold in the United States each year. Clearly, the Tobacco Industry's "Conspiracy of Death and Addiction" has been successful.

97. Not only did the Tobacco Industry know, misrepresent, omit and conceal that nicotine is an addictive drug, Plaintiffs and the Plaintiff Class are informed and believe that the Tobacco Industry requires that their cigarettes contain sufficient nicotine to satisfy addiction on the part of smokers, and therefore manipulates and controls the levels of nicotine in these products to create and sustain the addiction. It is this scheme to deceive the American public, including Plaintiffs and members of the Plaintiff Class, that enables the Tobacco Companies to not only sell its life threatening and addictive products to over two

http://legacy.library.ucsf.edu/tid/olr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/dgvl0001

million Ohio residents and citizens but more importantly, to make these Ohioans captive customers of the Tobacco Industry.

D. **The Tobacco Companies Manipulate the Level of Nicotine in Cigarettes With the Intent and Purpose of Creating and Sustaining Addictions to their Products.**

98. Plaintiffs and members of the Plaintiff Class are informed and believe that the Tobacco Companies control and/or manipulate the levels of nicotine in cigarettes and thus the amount of nicotine which can be absorbed into the human body from cigarette use. The Tobacco Companies developed technology years ago to remove and add nicotine from tobacco and to control precisely the amount of nicotine in cigarettes. Armed with this technology, the Tobacco Companies manufacture, market and sell their products with levels of nicotine that are sufficient to produce and sustain addiction. Rather than remove nicotine from cigarettes -- and hence remove the addictive drug contained therein - the Tobacco Companies add nicotine to their cigarettes, through a variety of methods, in order to maintain levels of nicotine sufficient to make their cigarettes addictive to consumers. In fact, in a 1972 internal memorandum, a Philip Morris research scientist summed up the real strategy moving the Tobacco Industry:

> Think of the cigarette as a dispenser for a dose unit of nicotine.

99. The Tobacco Companies prepare a substantial portion of the contents of their cigarettes through what is called a "reconstitution process." Prior to the 1940s, the waste products from

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cigarettes - tobacco leaf scraps and stems, dried tobacco dust, adhesive reinforcing fibers, mineral ash modifiers, humectants and other inexpensive materials -- were discarded. Thereafter, the Tobacco Companies began to use these previously unusable materials to make reconstituted tobacco. As part of the process, the Tobacco Companies removed ingredients from these materials at an early stage of the process and replaced some of the nicotine in later stages. The reconstitution process allows the Tobacco Companies to manufacture cigarettes more cheaply, by using less actual tobacco, which is the most expensive part of the cigarette, making up the difference by using reconstituted tobacco. By removing the nicotine and then replacing the nicotine to the levels required for addiction, the Tobacco Industry is able to control the precise amount of nicotine in cigarettes.

100. LTR Industries ("LTR"), a subsidiary of Kimberly-Clarke Corporation, specializes in the tobacco reconstitution process and, as LTR says, in helping tobacco companies "control" their nicotine. The LTR reconstitution process is the most widely used in the world. An LTR advertisement, entitled "More Nicotine, Or Less," published in tobacco trade publications states:

> Nicotine levels are becoming a growing concern to the designers of modern cigarettes, particularly those with lower "tar" deliveries. The Kimberly-Clarke tobacco reconstitution process used by LTR Industries, permits adjustments of nicotine to your exact requirements. These adjustments will not affect the other important properties of customized reconstituted tobacco produced at LTR Industries: low tar delivery, high filling power, high yield, and the flexibility to convey organoleptic modifi-

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> cations. We can help you control your tobacco.

In fact, the process described in the LTR advertisement can raise the level of nicotine beyond that which is naturally found in tobacco materials. In 1985, a Tobacco Journal article describing the LTR process provides: "Those standard reconstituted Tobacco Products contained 0.7-1.0 nicotine, LTR industries offers the possibility of increasing the nicotine content of the final sheet to a maximum of 3.5%.... A dramatic increase in tobacco taste and smoke is noted in the nicotine-fortified reconstituted tobacco."

101. Unbeknownst to cigarette smokers, the Tobacco Companies have long viewed cigarettes in terms of their nicotine delivery function. For example, Philip Morris' William L. Dunn Jr. wrote in a 1973 internal memorandum:

> Why then is there not a market for nicotine per se, to be eaten, sucked, drunk, injected, inserted or inhaled as a pure aerosol? The answer, and I feel quite strongly about this, is that the cigarette is in fact among the most awe-inspiring examples of the ingenuity of man...
>
> The cigarette should be conceived not as a product, but as a package. The product is nicotine. The cigarette is but one of many package layers. There is the carton, which contains the pack, which contains the cigarette, which contains the smoke. The smoke is the final package. The smoker must strip off all of these packaged layers to get to that which he seeks ... Think of the cigarette as a storage container for [a] days' supply of nicotine ... Think of the cigarette as a dispenser for a dose unit of nicotine .... Think of a puff of smoke as the vehicle for nicotine.... Smoke is beyond question the most optimized vehicle of nicotine and the ciga-

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> rette the most optimized dispenser of smoke.... (Emphasis supplied).

Likewise, a 1981 Lorillard study indicated that "current research is directed toward increasing the nicotine levels while maintaining or marginally reducing the 'tar' deliveries."

102. Evidence of the Tobacco Industry's intent and ability to manipulate nicotine and cigarettes at a sufficiently high level to provide the "desired physiological activity" is found in years of patent applications of the Tobacco Companies. These patents illustrate an intent and ability by the Tobacco Companies: (1) to control the amount of nicotine in cigarettes; (2) to provide desired physiological effects; (3) to increase nicotine content in cigarettes by adding nicotine to various parts of the cigarette; (4) to manipulate nicotine levels in cigarettes; and (5) to manipulate the rate at which the nicotine is delivered in the cigarettes. For example:

(a) A 1966 Philip Morris patent application discusses an invention that "permits the release into tobacco smoke, in controlled amounts, of desirable flavorants, as well as the release, in controlled amounts and when desired, of nicotine into tobacco smoke."

(b) A 1971 Philip Morris patent states:

> It has long been known in the Tobacco Industry that in order to provide a satisfactory smoke, it is desirable to maintain a nicotine content of Tobacco Products at a uniform level. However, it is difficult to accomplish this

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result since the nicotine content of tobacco varies widely, depending on the type of tobacco and the conditions under which the tobacco was grown.

Maintaining the nicotine content at a sufficiently high level to provide the desired physiological activity, taste, an odor which this material imparts to the smoke, without raising the nicotine content through an undesirably high level, can thus be seen to be a significant problem in the tobacco art. The addition of nicotine to tobacco in such a way that it remains inert and stable in the product and yet is released in a controlled amount into the smoke aerosol when the tobacco is pyrolyzed, is a result which is greatly desirable.

The present invention provides a solution to this longstanding problem and results in accurate control of the nicotine which is released in tobacco smoke. By employing the nicotine releasing agents in methods of the present invention, it is possible to incorporate exact amounts of nicotine into tobacco composition, which will remain constant over extended periods of time and which will ultimately yield a smoke containing a controlled amount of nicotine.

(c) Another 1971 Philip Morris patent application discusses a design to increase the nicotine content in the smoke of the tobacco product by adding nicotine. One of the expressed objects of the invention was to "provide an agent for the treatment of tobacco smoke whereby nicotine is easily released under controlled amounts." The same Philip Morris application explains that the proposed invention "is particularly useful for the maintenance of the proper amount of nicotine in tobacco smoke," and notes that "previous efforts have been made to add nicotine to Tobacco Products when the nicotine level in the tobacco was undesirably low."

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(d) A 1980 Loews' Corporation patent application discusses a process which "enables the manipulation of the nicotine content of tobacco material, such as cut leaf and reconstituted leaf, by removal of nicotine from a suitable nicotine tobacco source, or by the addition of nicotine to a low nicotine material."

(e) A 1986 RJR patent indicates that the Tobacco Companies can precisely manipulate the rate at which the nicotine is delivered in the cigarette: "It is a further object of this invention to provide a cigarette which delivers a larger amount of nicotine in the first few puffs of the cigarette than in the last few puffs."

(f) A 1991 RJR patent application states that "processed tobaccos can be manufactured under conditions suitable to provide products having various nicotine levels."

103. The Tobacco Companies' manipulation of the level of nicotine in cigarettes, with the intent and purpose of creating and sustaining addictions to their cigarettes, has only recently come to the public's attention.

104. During the March 25, 1994 Congressional Hearings, FDA Commissioner Dr. David Kessler testified that accumulating evidence suggests that the Tobacco Companies "may be controlling smokers' choice by controlling the level of nicotine in their products in a manner that creates and sustains an addiction in the vast majority of smokers." Dr. Kessler went on to say that some of "today's cigarettes may in fact, qualify as high technology nicotine

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delivery systems that deliver nicotine in precisely calculated quantities -- quantities that are more than sufficient to create and sustain an addiction in the vast majority of individuals who smoke regularly." During the March 25 Hearing, Dr. Kessler and others presented evidence of the Tobacco Companies' manipulation of nicotine levels, including reference to internal memoranda and more than 30 industry patents, several of which have been identified above.

105. Just as the Tobacco Companies deny that the nicotine contained in cigarettes is addictive, through their individual advertising and public relations campaigns and collectively through the Tobacco Institute, the Tobacco Companies have denied unequivocally that they are engaged in controlling the level of nicotine in cigarettes for the purpose of developing and sustaining addiction to their products. Since the March 25, 1994 Congressional Hearings, in nationwide television broadcasts and publications, spokespersons for the Tobacco Institute, the Tobacco Companies and therefore the Tobacco Industry have denied and sought to refute all charges that the Tobacco Companies manipulate nicotine levels in cigarettes. During their appearance before Congress on April 14, 1994, the chief executives of each of the Tobacco Companies testified that their companies do not manipulate nicotine levels in or otherwise add nicotine to their cigarettes to create or sustain addiction to their products.

106. The nicotine content of the raw tobacco is not the only variable manipulated by the Tobacco Companies to deliver a

pharmacologically active dose of nicotine to the smoker. Cigarettes are not simply cut tobacco rolled into a paper tube. Modern cigarettes as sold in Ohio are painstakingly designed and manufactured to control nicotine delivery to the smoker.

107. For example, the Tobacco Companies add several ammonia compounds during the manufacturing process which increase the delivery of nicotine and almost double the nicotine transfer efficiency of cigarettes.

108. In furtherance of the Tobacco Industry conspiracy and in an attempt to both perpetrate a fraud upon Plaintiffs and members of the Plaintiff Class as well as to violate Ohio's Consumer Protection Statutes, Brown & Williamson has publicly denied that the use of ammonia in the processing of tobacco increases the amount of nicotine absorbed by the smoker. However, the company's own internal documents reveal that Brown & Williamson and the other Tobacco Companies use ammonia compounds to increase nicotine delivery. A 1991 Brown & Williamson confidential blending manual states:

> Ammonia, when added to a tobacco blend, reacts with the indigenous nicotine salts and liberates free nicotine ... As the result of such change the ratio of extractable nicotine to bound nicotine in the smoke may be altered in favor of extractable nicotine. As we know, extractable nicotine contributes to impact in cigarette smoke and this is how ammonia can act as an impact booster.

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According to Brown & Williamson's secret manual, all American cigarette manufacturers except Liggett use ammonia technology in their cigarettes.

FIRST CLAIM FOR RELIEF
[Fraud And Deceit]

109. Plaintiffs, on behalf of themselves, the Plaintiff Class and all others similarly situated, reallege, as if fully set forth, each and every allegation contained in paragraphs 1 through 109 above, and further allege:

110. At all times during the course of dealing between Defendants and Plaintiffs and the members of the Plaintiff Class, through advertising and representations in the mass media and by other communications, Defendants have repeatedly misrepresented and concealed the fact that nicotine is not addictive. Moreover, under oath, the Tobacco Industry has repeatedly stated to Congress that the Tobacco Industry does not manipulate nicotine levels in their cigarettes so as to addict or maintain the addiction of consumers including Plaintiffs and members of the Plaintiff Class.

111. In representations to the American public which includes Plaintiffs and members of the Plaintiff Class, Defendants intentionally omitted the following material information: nicotine is addictive and the Tobacco Companies manipulate nicotine levels in their cigarettes so as to addict consumers such as Plaintiffs and members of the Plaintiff Class.

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112. Defendants were under a duty to disclose to Plaintiffs and Plaintiff Class members the addictive nature of nicotine, Defendants' manipulation of the nicotine levels in Defendants' cigarettes, and Defendants' intent to addict Plaintiffs and the Plaintiff Class members. Defendants had sole access to nonpublic material facts, which remained in the exclusive possession, custody and control of the Tobacco Industry, concerning: (1) the addictive nature of nicotine, (2) the manipulation of nicotine levels in their cigarettes, and (3) the Tobacco Industry's intent to addict or maintain the addiction of Plaintiffs and the Plaintiff Class members. Defendants knew that, prior to Plaintiffs' addiction to nicotine, Plaintiffs and Plaintiff Class members could not reasonably have discovered the addictive nature of nicotine, Defendants' manipulation of the nicotine levels in Defendants' cigarettes, and Defendants' intent to addict or maintain the addiction of Plaintiffs and the Plaintiff Class members.

113. The Tobacco Industry knew, or reasonably should have known that this information was crucial to Plaintiffs and members of the Plaintiff Class in making their decision to purchase cigarettes. As a result, Plaintiffs and members of the Plaintiff Class were deprived of informed consent regarding their ingestion of an addictive drug, and were deprived of any choice in which to make a risk benefit assessment to the detriment of Plaintiffs and members of the Plaintiff Class. In addition, Defendants actively concealed the addictive nature of nicotine, Defendants' manipulation of nicotine levels in Defendants' cigarettes, and

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Defendants' intent to addict or maintain the addiction of Plaintiffs and the Plaintiff Class members. As specifically set forth in paragraphs 35 through 109 herein, the misrepresentations, omissions and concealments of the Tobacco Industry includes, but are not limited to:

a. Testifying falsely under oath before the United States Congress;

b. Providing false explanations to customers and to governmental entities regarding the health hazards of tobacco and the addictive qualities of nicotine;

c. Conducting activities in furtherance of the conspiracy in secret, including clandestine meetings, using Tobacco Company attorneys to secure documents that might reveal the dangers of cigarettes and the addictive nature of nicotine, closing down research projects and moving research and information facilities outside the United States; and

d. Requiring employees of the Tobacco Industry to keep secret all information about the dangers of cigarette smoking and the addictive nature of nicotine under threats of severe legal consequences.

114. The representations, omissions and concealments were false when made and Defendants knew or were reckless in not knowing and reasonably should have known that they were false. In fact, nicotine was known to Defendants to be addictive, the level of

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nicotine in Defendants' cigarettes was known to be manipulated by Defendants, and the intent to addict or maintain the addiction of Plaintiffs and Plaintiff Class members was known to Defendants.

115. The misrepresentations, omissions and concealments were made deliberately, willfully, maliciously and/or recklessly with the intent to mislead Plaintiffs and the members of the Plaintiff Class into reliance upon them and were material in causing Plaintiffs and members of the Plaintiff Class to purchase Defendants' cigarettes.

116. Plaintiffs and the members of the Plaintiff Class had no way to determine that the misrepresentations and concealments were false and misleading, and that they included material omissions, and Plaintiffs and members of the Plaintiff Class reasonably relied thereon.

117. Specifically, until shortly before the filing of the Complaint in this action, Plaintiff and members of the Plaintiff Class had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent and active concealment and omission of the wrongdoing by Defendants, including deliberate efforts -- which continue to this day -- to give Plaintiff and members of the Plaintiff Class the materially false impression that nicotine is not addictive and that Defendants are not manipulating the nicotine levels of their cigarettes, Plaintiff and members of the Plaintiff Class could not reasonably have discovered the wrongdoing at any time prior to the filing of the

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instant Complaint. Defendants have attempted and are continuing their attempts to keep such internal information from reaching Plaintiffs and members of the Plaintiff Class. Indeed, Defendants in furtherance of their fraud and conspiracy continue to refuse to admit that nicotine is addictive and that the Tobacco Industry has manipulated the levels of nicotine in their cigarettes.

118. As a proximate and direct result of their reliance on Defendants' misrepresentations, omissions and concealments, Plaintiffs and the members of the Plaintiff Class are addicted or in danger to become addicted to cigarettes, have suffered severe emotional distress, have incurred economic damages including medical expenses and/or lost wages and have been otherwise damaged. Plaintiffs and the Plaintiff Class members are therefore entitled to the relief requested herein including but not limited to the equitable relief described in the Eleventh Claim for Relief and to damages according to proof.

119. Defendants knew that nicotine was addictive, Defendants manipulated the amount of nicotine level in Defendants' cigarettes, and Defendants intended to addict Plaintiffs and the Plaintiff Class members by failing to disclose material facts to Plaintiffs and the Plaintiff Class members, for the purpose of inducing them to purchase cigarettes, thus causing them to incur economic and other damages in an amount to be proven at trial.

120. Defendants are liable for punitive damages for their reckless or wanton or willful disregard for the safety of the

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general public, including but not limited to Plaintiffs and members of the Plaintiff Class in the manipulation of nicotine, a toxic and hazardous substance in their cigarettes along with the concealment and denial of nicotine's addictive properties, all done to maximize sales and profit by creating a self generating market for cigarettes by addicting Plaintiffs and members of the Plaintiff Class to nicotine. Defendants' conduct constitutes malice, oppression, and fraud and thereby warrants the imposition of punitive and exemplary damages against Defendants as provided by Ohio law.

SECOND CLAIM FOR RELIEF
[Conspiracy]

121. Plaintiffs, on behalf of themselves, the Plaintiff Class and all others similarly situated, reallege, as if fully set forth, each and every allegation contained in paragraphs 1 through 121 above, and further allege:

122. As set forth more fully in paragraphs 35 through 109 herein, beginning in the early 1950's and continuing until the present day, Defendants American Tobacco, RJR, Brown & Williamson, Philip Morris, Liggett & Myers, Lorillard, the CTR and the Tobacco Institute, individually and acting in concert with one another, entered into a malicious combination with the intentional and unlawful purpose and effect of restraining and suppressing research and material information on the harmful effects of smoking; restraining and suppressing the dissemination of research and

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material information on both the addictive effects of nicotine and the manipulation of the levels of nicotine in cigarettes and the harmful effects of smoking; engaging in affirmative misrepresentations, omissions and concealments of the addictive effects of nicotine and the harmful effects of smoking; failing to inform Plaintiff and members of the Plaintiff Class of the addictive nature of nicotine and the manipulation of the levels of nicotine in cigarettes; restraining and suppressing the research, development, production, and marketing of a "safer" cigarette; and the intentional violations of Ohio's Product Liability Law and Ohio's Consumer Protection statutes including but not limited to O.R.C. §1345.02, O.R.C. §1345.03 and O.R.C. §4165.02. ("Ohio Consumer Protection Act"). In furtherance of this "Conspiracy of Death and Addiction," the individual members of the Tobacco Industry lent encouragement, substantial assistance, and otherwise aided and abetted each other with respect to these wrongful acts.

123. Defendants by tacit and/or express agreement, cooperation and by a common design and understanding, actively participated in the tortious acts set forth in paragraphs 35 through 109 herein in order to defraud Plaintiffs and members of the Plaintiff Class and/or violate Ohio's Consumer Protection Act and/or to manufacture, market, advertise and/or sell defective cigarettes in violation of the Ohio product liability statutes, or lent aid to the wrongdoers, or ratified or adopted the acts done for their benefit, by intentionally restraining and suppressing the dissemination of information on the addictive effects of nicotine,

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the manipulation of nicotine levels in cigarettes and the harmful effects of smoking and by omitting this information in statements and publications available to Plaintiffs and members of the Plaintiff Class.

124. As a direct and proximate result of Defendants' unlawful conspiracy, and in addition to the injuries suffered by Plaintiffs and members of the Plaintiff Class from the other independent tortious conduct set forth in this Complaint, the Plaintiffs and members of the Plaintiff Class have suffered addiction, severe emotional distress, economic damages, including medical expenses and/or lost wages, and have otherwise been damaged.

125. As a result of Defendants' conspiracy, Defendants are vicariously, jointly and severally liable with respect to each cause of action described above.

126. Defendants' conduct exhibits such an entire want of care as to establish that their actions were a result of fraud, ill will, recklessness, or willful and intentional disregard of the rights of Plaintiffs and members of the Plaintiff Class. Therefore, the Plaintiffs and members of the Plaintiff Class are entitled to punitive and exemplary damages.

127. The Plaintiffs and members of the Plaintiff Class are therefore entitled to compensatory damages in an amount to be proven at trial, along with punitive damages, attorney fees plus pre and post judgment interest and costs.

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THIRD CLAIM FOR RELIEF
[Negligent Misrepresentation]

128. Plaintiffs, on behalf of themselves, the Plaintiff Class and all others similarly situated, reallege, as if fully set forth, each and every allegation contained in paragraphs 1 through 128 above, and further allege:

129. By reason of their knowledge and expertise regarding the addictive nature of nicotine, manipulation of the amount of nicotine level in Defendants' cigarettes, and intent to addict, and by reason of their statements to consumers in advertisements and other communications, at all times relevant hereto, Defendants owed Plaintiffs and the members of the Plaintiff Class a duty of care which required, among other things, that Defendants be truthful and accurate in their representations to Plaintiffs and members of the Plaintiff Class concerning their cigarettes.

130. Defendants breached their duty of care to consumers by negligently making the material misrepresentations alleged in the First Claim for Relief.

131. Plaintiffs and the members of the Plaintiff Class reasonably relied on Defendants' representations, when in fact those representations constituted negligent misrepresentations.

132. Such reliance was not only foreseeable by Defendants but also intended by them.

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133. By reason of their reliance on the Defendants' negligent misrepresentations, Plaintiffs and the members of the Plaintiff Class are addicted or subject to being addicted to cigarettes, have suffered severe emotional distress, have incurred economic damages, including medical expenses and/or lost wages and have been otherwise damaged. Plaintiffs and the Plaintiff Class members are therefore entitled to the equitable relief described in the Eleventh Claim for Relief and to damages according to proof.

FOURTH CLAIM FOR RELIEF
[Intentional Infliction of Emotional Distress]

134. Plaintiffs, on behalf of themselves, the Plaintiff Class and all others similarly situated, reallege, as if fully set forth, each and every allegation contained in paragraphs 1 through 134 hereof, and further allege:

135. Defendants acted in an extreme and outrageous manner towards the Plaintiffs and the members of the Plaintiff Class through a course of conduct which included denying that nicotine is addictive while manipulating the levels of nicotine in their cigarettes so as to addict or maintain the addiction of Plaintiffs and the members of the Plaintiff Class to Defendants' cigarettes. Defendants acted with the intention of causing, or with reckless disregard of the probability of causing, emotional distress to Plaintiffs and members of the Plaintiff Class.

136. As a direct, foreseeable, actual and proximate result of the Defendants' conduct, Plaintiffs have suffered and continue to

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suffer addiction, severe emotional distress, economic damages, including medical expenses and/or lost wages and have been otherwise damaged for which they are entitled to damages according to proof. Plaintiffs' injuries are serious and of a nature that no reasonable man could be expected to endure.

137. At all times relevant hereto, Defendants' conduct was intentional and/or outrageous and beyond the bounds of reasonableness and was in reckless disregard for the safety of Plaintiffs and the Plaintiff Class. Plaintiffs and the Plaintiff Class are therefore entitled to punitive and exemplary damages.

FIFTH CLAIM FOR RELIEF
[Negligence]

138. Plaintiffs, on behalf of themselves, the Plaintiff Class and all others similarly situated, reallege, as if fully set forth, each and every allegation contained in paragraphs 1 through 138 hereof, and further allege:

139. At all times relevant to the instant Complaint, the individual Defendants acting alone or in concert and conspiracy with one another, through research and studies such as Brown & Williamson's Project Wheat and the Special Projects Division of the Council for Tobacco Research, had actual and/or constructive knowledge or reasonably should have known that the cigarettes and/or other tobacco products which were designed, manufactured, supplied and placed into the public domain for consumption by Plaintiffs and the Plaintiff Class were dangerous or likely to be

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dangerous due to the addictive levels of nicotine which had been manipulated and placed into the cigarettes and/or other tobacco products by the Tobacco Companies.

140. Due to the secretive methods, manner and means in which the Tobacco Companies suppressed, failed and refused to disclose the dangerously addictive nature of the manipulated levels of nicotine in the cigarettes of the Tobacco Companies, the Tobacco Companies knew and had no reason to believe that the Plaintiffs and members of the Plaintiff Class would have no knowledge of the dangerous condition of the cigarettes supplied by the Tobacco Companies to Plaintiffs and the Plaintiff Class.

141. The Defendants, acting alone or in concert and conspiracy with one another, failed to act in a reasonable and prudent manner and exercise reasonable and ordinary care to inform and warn Plaintiffs and members of the Plaintiff Class of the dangerous nature and condition of cigarettes which contained addictive levels of nicotine or of the facts underlying the dangerous nature and condition of their cigarettes and other tobacco products.

142. The Defendants, acting alone or in concert and conspiracy with one another, knew or reasonably should have known that their failure to warn Plaintiffs and members of the Plaintiff Class of the dangerously addictive nature of the manipulated levels of nicotine in their cigarettes was likely to result in the addiction of Plaintiffs and members of the Plaintiff Class with the resultant adverse health problems.

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143. Due to the foreseeability of the harm to Plaintiffs and members of the Plaintiff Class, Defendant Tobacco Companies had a duty to Plaintiffs and Plaintiff Class members to provide a reasonably safe product in design and manufacture, and to warn of the addictive nature of nicotine.

144. Defendants breached their duty of reasonable care to Plaintiffs and Plaintiff Class members by the following acts and omissions:

(a) failure to design and manufacture cigarettes that were not addictive and/or that did not contain unreasonable levels of nicotine;

(b) failure to warn consumers of the addictive nature of nicotine when they knew or should have known of nicotine's addictive nature; and

(c) otherwise failing to exercise due care under the circumstances.

145. As a direct and proximate result of the carelessness and negligence of Defendants, Plaintiffs and Plaintiff Class members have suffered addiction, severe emotional distress, economic damages including medical expenses and/or lost wages and have otherwise been damaged.

SIXTH CLAIM FOR RELIEF
[Negligent Infliction Of Serious Emotional Distress]

146. Plaintiffs, on behalf of themselves, the Plaintiff Class and all others similarly situated, reallege, as if fully set forth, each and every allegation contained in paragraphs 1 through 146 hereof, and further allege:

147. As set forth more fully in this Complaint and specifically in the Fifth Claim for Relief above, the Tobacco Industry acted negligently by supplying Plaintiffs and members of the Plaintiff Class with cigarettes which were dangerous due to the addictive levels of nicotine which had been manipulated and placed into these products by the Tobacco Companies, without informing and warning Plaintiffs and members of the Plaintiff Class of the dangerous nature and condition of the cigarettes.

148. As a direct and proximate result of the negligence of Defendants, Plaintiffs and members of the Plaintiff Class have suffered and continue to suffer addiction and emotional distress so severe and serious that Plaintiffs and members of the Plaintiff Class cannot be reasonably expected to adequately cope with this serious emotional distress, economic damages including medical expenses and/or lost wages and have otherwise been damaged.

149. It was reasonably foreseeable by the Tobacco Industry that the addictive nature of the nicotine manipulated and placed into cigarettes by the Tobacco Companies would directly result in serious emotional problems due to the unwanted addiction to

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nicotine, and therefore cigarettes, of the Plaintiffs and members of the Plaintiff Class.

SEVENTH CLAIM FOR RELIEF
[Violation of Consumer Protection Statutes]

150. Plaintiffs, on behalf of themselves, the Plaintiff Class and all others similarly situated, reallege, as if fully set forth, each and every allegation contained in paragraphs 1 through 150 above, and further allege:

151. Plaintiffs and Plaintiff Class members are consumers who purchased Defendants' cigarettes for personal use. Ohio has enacted O.R.C. §1345.02, O.R.C. §1345.03 and O.R.C. §4165.02 to protect consumers against unfair, deceptive or fraudulent business practices, unfair competition, and false advertising and unconscionable acts and practices. Ohio allows consumers a private right of action for damages and/or equitable relief under these statutes.

152. By their conduct, including manipulation of nicotine levels, suppression, subversion and distortion of medical and scientific research, misrepresentations and non-disclosures of material facts alleged above, Defendants deceived and continue to deceive consumers and subject them to continuing and/or increasing addiction to Defendants' cigarettes. This conduct constitutes unlawful, unfair, unconscionable, deceptive and fraudulent business practices within the meaning of O.R.C. §1345.02, O.R.C. §1345.03 and O.R.C. §4165.02.

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153. In addition, Defendants' use of various media to promote the sale of Defendants' cigarettes by, among other things, falsely and deceptively representing that nicotine is not addictive and that Defendants' do not manipulate the levels of nicotine in their cigarettes so as to addict or maintain the addiction of consumers constitutes unfair competition and unfair, deceptive, untrue, or misleading advertising within the meaning of state consumer protection statutes.

154. The above-described unlawful, unfair, and fraudulent business practices, false and misleading advertising, and unfair competition by Defendants continues to present a threat to members of the public. Defendants have systematically perpetrated a fraud upon members of the public and refuse publicly to acknowledge the wrongdoing of their actions. Defendants continue to refuse to admit that nicotine is addictive, that Defendants manipulate the amount of nicotine level in Defendants' cigarettes, or that Defendants intend Plaintiffs and Plaintiff Class members to become or remain addicted to nicotine.

155. As a result of the conduct described above, Defendants have been and will continue to be unjustly enriched at the expense of Plaintiffs and the members of the Plaintiff Class. Specifically, Defendants have been unjustly enriched by the receipt of billions of dollars in domestic cigarettes sales each year, which products were promoted and sold through advertisements and statements which affirmatively misrepresent, either directly or by implication, that nicotine is not addictive and that the Tobacco

Companies do not manipulate the nicotine levels of their cigarettes so as to addict or maintain the addiction of consumers.

156. Plaintiffs and the members of the Plaintiff Class are therefore entitled to the equitable relief described below in the Eleventh Claim for Relief along with compensatory damages and attorneys' fees.

EIGHTH CLAIM FOR RELIEF
[Breach of Express Warranty]

157. Plaintiffs, on behalf of themselves, the Plaintiff Class and all others similarly situated, reallege, as if fully set forth, each and every allegation contained in paragraphs 1 through 157 hereof, and further allege:

158. Defendants' advertisements and promotional statements alleged above contained broad promises and affirmations of facts claims amounting to a warranty that Defendants' cigarettes were not addictive, that the Tobacco Companies did not manipulate the nicotine levels in Defendants' cigarettes, and that Defendants did not intend to addict or maintain the addiction of Plaintiffs and Plaintiff Class members. These promises and affirmations of facts were such that a reasonable person in the position of Plaintiffs would believe Defendants had made a promise as to the performance of their cigarettes or made affirmations of facts about the condition of their cigarettes.

159. As alleged above, the Tobacco Companies breached their warranties by offering for sale, and selling as non-addictive,

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cigarettes that were addictive, and contained levels of nicotine manipulated by the Tobacco Companies to make them addictive.

160. Defendants' breach of their express warranties has caused Plaintiffs and the Class members to become addicted or remain addicted to nicotine and entitles them to equitable relief as described in the Eleventh Claim for Relief and has caused Plaintiffs and the members of the Class to suffer damages in an amount to be proven at trial.

NINTH CLAIM FOR RELIEF
[Breach of Implied Warranty]

161. Plaintiffs, on behalf of themselves, the Plaintiff Class and all others similarly situated, reallegè, as if fully set forth, each and every allegation contained in paragraphs 1 through 161 above, and further allege:

162. The Tobacco Companies impliedly warranted that their cigarettes, which they designed, manufactured, and sold to Plaintiffs and members of the Plaintiff Class, were merchantable and fit and safe for their ordinary use, and that the Tobacco Companies have not manipulated their nicotine levels so as to make them addictive to consumers such as Plaintiffs and members of the Plaintiff Class. Not only did Plaintiffs and members of the Plaintiff Class rely upon these implied warranties but the Tobacco Companies knew or reasonably should have known that Plaintiffs and members of the Plaintiff Class would rely upon these implied warranties when purchasing cigarettes.

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163. The cigarettes purchased and consumed by Plaintiffs and the members of the Plaintiff Class were addictive, unmerchantable, and unfit for use when sold, and subjected Plaintiffs and members of the Plaintiff Class to addiction and/or increasing addiction. Therefore, the Tobacco Companies breached the implied warranty of merchantability at the time the cigarettes were sold to Plaintiffs and Plaintiff Class members in that the cigarettes were not fit for their ordinary purposes.

164. Defendants Novelart and EBY-Brown are liable as wholesale distributors of products for resale in Ohio.

165. Defendants Kroger and Riser are liable as retail distributors of products for sale in Ohio.

166. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiffs and Plaintiff Class members are addicted or subject to addiction to Defendants' cigarettes and entitled to the equitable relief described in the Eleventh Claim for Relief and have suffered addiction, severe emotional distress, economic damages and have otherwise been damaged.

TENTH CLAIM FOR RELIEF
[Strict Product Liability]

167. Plaintiffs, on behalf of themselves, the Plaintiff Class and all others similarly situated, reallege, as if fully set forth, each and every allegation contained in paragraphs 1 through 167 above, and further allege against the Tobacco Companies:

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168. At all relevant times, the Tobacco Companies were engaged in the business of manufacturing and selling their cigarettes for ultimate retail sale to consumers. These Defendants manufactured their cigarettes, manipulated the level of nicotine in their cigarettes and together with the other Defendants sold these cigarettes to retailers, who sold them to Plaintiffs and Plaintiff Class members.

169. Defendants' cigarettes were expected to and did reach the Class without substantial change in their condition as manufactured, manipulated and sold by the manufacturing Defendants and wholesale Defendants, Novelart and EBY-Brown, along with retail Defendants, Kroger and Riser, aided and abetted in the sale of addictive products to the Plaintiff Class members. Thus, the defect alleged below, existed when the product left Defendant's possession.

170. The Plaintiffs and the Class members reasonably and foreseeably consumed the cigarettes in the manner in which the cigarettes were intended to be used, that is, for personal consumption, causing and/or subjecting Plaintiffs and Plaintiff Class members to become addicted to nicotine.

171. The members of the Class were not aware of, and could not in the exercise of reasonable care have discovered, the addictive nature of cigarettes, Defendants' manipulation of the nicotine levels of these cigarettes, and Defendants' intent to addict or maintain the addiction of Plaintiffs and Plaintiff Class members

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because they were marketed and sold without reasonable warnings of their dangers. These dangers, as alleged above, were known, or should have been known to Defendants, who manufactured and sold addictive products to Plaintiffs.

172. Because Plaintiffs and members of the Plaintiff Class could not have discovered the addictive nature of cigarettes at the time they purchased and consumed Defendants' cigarettes and because Plaintiffs and Plaintiff Class members subsequently suffered and continue to suffer from the addictive effects of these cigarettes, Defendants' cigarettes failed to perform as safely as Plaintiffs, as ordinary consumers of Defendants products would have expected and/or the foreseeable risks associated with the cigarettes' design exceeded the benefits associated with that design.

173. As a direct and proximate result of Defendants' design, manufacture, promotion, marketing and sale of Defendants' cigarettes, Plaintiffs and the Plaintiff Class members have suffered addiction or are subject to addiction to Defendants' cigarettes and have suffered severe emotional distress, economic damages and have otherwise been damaged.

174. Defendants' cigarettes, containing manipulated levels of nicotine, as manipulated by manufacturing Defendants, which caused or subjected Plaintiffs and Plaintiff Class members to become addicted to nicotine upon personal consumption, constitute a product dangerous for normal use due to their defective design,

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defective manufacture, and Defendants' inadequate warnings to the Plaintiff Class.

175. Thus, Defendants are strictly liable to Plaintiffs and Plaintiff Class members in an amount according to proof.

176. The Tobacco Companies which manufactured the cigarettes and the Wholesale/Retail Defendants who sold the cigarettes in a defective condition unreasonably dangerous to consumers are strictly liable for the harm caused therefrom because these Defendants are engaged in the business of selling such a product, i.e., cigarettes and the cigarettes were expected to and did reach consumers without substantial change in the condition in which they were manufactured and sold.

177. Pursuant to Ohio Revised Code §2307.78(A)(1), the Defendants who acted as wholesale and retail suppliers/distributors of the cigarettes have incurred liability for compensatory damages based on the product liability claims stated in paragraphs 168 to 177 above, as these Defendants:

(a) negligently failed to warn, advise, or instruct consumers of the cigarettes of the design and manufacturing defects which should have been known to these Defendants since, at a minimum 1988, the year the Surgeon General's Report "The Health Consequences of Smoking: Nicotine Addiction" was published;

(b) negligently supplied, distributed, and/or sold the cigarettes when they knew or should have known of the design and manufacturing defects which should have been known to these Defendants since, at a minimum 1988, the year the Surgeon General's Report "The Health Consequences of Smoking: Nicotine Addition" was published.

As a direct and proximate result of these Defendants' negligent conduct, Plaintiffs and members of the Plaintiff Class have suffered addiction, severe emotional distress, have incurred economic damages including medical expenses and/or lost wages and have otherwise been damaged.

178. Brown & Williamson is further liable pursuant to Ohio Revised Code §2307.78 as a supplier as it has acted as a wholesale distributor of cigarettes within the state of Ohio.

ELEVENTH CLAIM FOR RELIEF
[Equitable (Injunctive and/or Declaratory) Relief]

179. Plaintiffs, on behalf of themselves, the Plaintiff Class and all others similarly situated, reallege, as if fully set forth, each and every allegation contained in paragraphs 1 through 178 above, and further allege:

180. The Plaintiff Class members have no adequate remedy at law, rendering injunctive and other equitable relief appropriate in that damages cannot adequately compensate Plaintiffs and Plaintiff Class members for the injuries suffered and threatened.

181. Accordingly, Plaintiffs, on behalf of themselves and all others similarly situated, request the following class-wide equitable relief:

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(a) that a judicial determination and declaration be made of the rights of Plaintiffs and the Plaintiff Class members, and the corresponding responsibilities of Defendants;

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(b) that Defendants be declared to be financially responsible for notifying all Plaintiffs and members of the Plaintiff Class of nicotine's addictive nature, Defendants' manipulation of nicotine levels in their cigarettes, and Defendants' intent to addict or maintain the addiction of Plaintiffs and Plaintiff Class members, with restitution and refunds to Plaintiffs and the Plaintiff Class members of all or part of the sums paid by them to purchase Defendants' falsely promoted cigarettes;

(c) that Defendants be ordered to disgorge, for the benefit of the Plaintiff Class, all or part of their ill-gotten profits received from the sale of cigarettes and/or to make full restitution to the Plaintiffs and Plaintiff Class members; and

(d) that Defendants be ordered to create a medical monitoring fund, under the continuing jurisdiction and supervision of the Court, to monitor the health of Plaintiffs and Plaintiff Class members and to pay or reimburse Plaintiff Class members for all medical expenses caused by Defendants' wrongdoing. Cigarette smokers are entitled to a "medical monitoring" fund because, as a result of the addictive nature of nicotine in cigarettes, they are at risk for addiction-related physical, mental and emotional harm and are demonstrably at increased risk for lung disease, heart disease, and other well-established smoking-related ailments. Due to the demonstrably addictive properties of nicotine and the levels designed and delivered by Defendants in their cigarettes, the need for ongoing monitoring is a reasonably certain consequence of

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Plaintiff Class members' exposure to nicotine and all other harmful or carcinogenic ingredients in cigarettes, and the recommended monitoring is reasonable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, pray for judgment against Defendants, and each of them, jointly and severally as follows:

1. An Order certifying the Class and any appropriate subclass thereof under the appropriate provisions of Civil Rule 23, and appointing Plaintiffs and their counsel to represent the Class;

2. For the equitable relief requested in the Ninth Claim for Relief;

3. For compensatory damages in excess of $25,000 as alleged herein;

4. For punitive or exemplary damages against each Defendant found liable of oppression, fraud, malice, recklessness and/or despicable behavior, in an amount sufficient to punish each such Defendant and deter others from similar wrongdoing;

5. For all applicable statutory damages (including multiple damages and punitive damages) under the consumer and buyer protection statutes of Ohio;

6. For medical monitoring, whether denominated as damages or in the form of equitable relief;

7. For attorneys' fees;

8. For pre-judgment and/or post judgment interest;

9. For costs of suit; and

10. For such other and further relief as this Court may deem just and proper pursuant to Civil Rule 54(c).

JURY DEMAND

Plaintiffs demand a trial by jury on all claims so triable.

Respectfully submitted,

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Diagnostic and Statistical Manual of Mental Disorders

Fourth Edition

DSM-IV™



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Criteria for Substance Dependence

A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring at any time in the same 12-month period:

(1) tolerance, as defined by either of the following:
  (a) a need for markedly increased amounts of the substance to achieve intoxication or desired effect
  (b) markedly diminished effect with continued use of the same amount of the substance

(2) withdrawal, as manifested by either of the following:
  (a) the characteristic withdrawal syndrome for the substance (refer to Criteria A and B of the criteria sets for Withdrawal from the specific substances)
  (b) the same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms

(3) the substance is often taken in larger amounts or over a longer period than was intended

(4) there is a persistent desire or unsuccessful efforts to cut down or control substance use

(5) a great deal of time is spent in activities necessary to obtain the substance (e.g., visiting multiple doctors or driving long distances), use the substance (e.g., chain-smoking), or recover from its effects

(6) important social, occupational, or recreational activities are given up or reduced because of substance use

(7) the substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance (e.g., current cocaine use despite recognition of cocaine-induced depression, or continued drinking despite recognition that an ulcer was made worse by alcohol consumption)

Specify if:

With Physiological Dependence: evidence of tolerance or withdrawal (i.e., either Item 1 or 2 is present)

Without Physiological Dependence: no evidence of tolerance or withdrawal (i.e., neither Item 1 nor 2 is present)

Course specifiers (see text for definitions):

Early Full Remission
Early Partial Remission
Sustained Full Remission
Sustained Partial Remission
On Agonist Therapy
In a Controlled Environment

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DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS

FOURTH EDITION

DSM-IV™



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WASHINGTON, DC

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Differential Diagnosis

For a general discussion of the differential diagnosis of Substance-Related Disorders, see p. 190. Inhalant-Induced Disorders may be characterized by symptoms (e.g., depressed mood) that resemble **primary mental disorders** (e.g., Major Depressive Disorder versus Inhalant-Induced Mood Disorder. With Depressive Features. With Onset During Intoxication). See p. 193 for a discussion of this differential diagnosis.

The symptoms of mild to moderate Inhalant Intoxication can be similar to those of **Alcohol Intoxication** and **Sedative, Hypnotic, or Anxiolytic Intoxication.** Breath odor or residues on body or clothing may be important differentiating clues, but should not be relied on exclusively. Individuals who chronically use inhalants are likely to use other substances frequently and heavily, further complicating the diagnostic picture. Concomitant use of alcohol may also make the differentiation difficult. History of the drug used and characteristic findings (including odor of solvent or paint residue) may differentiate Inhalant Intoxication from other substance intoxications; additionally, symptoms may subside faster with Inhalant Intoxication than with other substance intoxications. Rapid onset and resolution may also differentiate Inhalant Intoxication from other mental disorders and neurological conditions. Inhalant Intoxication is distinguished from the **other Inhalant-Induced Disorders** (e.g., Inhalant-Induced Mood Disorder. With Onset During Intoxication) because the symptoms in these latter disorders are in excess of those usually associated with Inhalant Intoxication and are severe enough to warrant independent clinical attention.

Industrial workers may occasionally be **accidentally exposed to volatile chemicals** and suffer physiological intoxication. The category "Other Substance–Related Disorders" should be used for such toxin exposures.

292.9 Inhalant-Related Disorder Not Otherwise Specified

The Inhalant-Related Disorder Not Otherwise Specified category is for disorders associated with the use of inhalants that are not classifiable as Inhalant Dependence, Inhalant Abuse, Inhalant Intoxication, Inhalant Intoxication Delirium, Inhalant-Induced Persisting Dementia, Inhalant-Induced Psychotic Disorder, Inhalant-Induced Mood Disorder, or Inhalant-Induced Anxiety Disorder.

Nicotine-Related Disorders

Nicotine Dependence and Withdrawal can develop with use of all forms of tobacco (cigarettes, chewing tobacco, snuff, pipes, and cigars) and with prescription medications (nicotine gum and patch). The relative ability of these products to produce Dependence or to induce Withdrawal is associated with the rapidity characteristic of the route of administration (smoked over oral over transdermal) and the nicotine content of the product.

This section contains discussions specific to the Nicotine-Related Disorders. Texts and criteria sets have already been provided to define the generic aspects of Substance Dependence (p. 176) that apply across all substances. Text specific to Nicotine Dependence is provided below. Nicotine intoxication and nicotine abuse are not

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included in DSM-IV: nicotine intoxication rarely occurs and has not been well studied, and nicotine abuse is not likely to be observed in the absence of Dependence. A specific text and criteria set for Nicotine Withdrawal is also provided below. Listed below are the Nicotine-Related Disorders.

Nicotine Use Disorder

305.10 Nicotine Dependence (see p. 243)

Nicotine-Induced Disorder

292.0 Nicotine Withdrawal (see p. 244)

292.9 Nicotine-Related Disorder Not Otherwise Specified (see p. 247)

Nicotine Use Disorder

305.10 Nicotine Dependence

Also refer to the text and criteria for Substance Dependence (see p. 176). Some of the generic Dependence criteria do not appear to apply to nicotine, whereas others require further explanation. Tolerance to nicotine is manifested by the absence of nausea, dizziness, and other characteristic symptoms despite using substantial amounts of nicotine or a diminished effect observed with continued use of the same amount of nicotine-containing products. Cessation of nicotine use produces a well-defined withdrawal syndrome that is described below. Many individuals who use nicotine take nicotine to relieve or to avoid withdrawal symptoms when they wake up in the morning or after being in a situation where use is restricted (e.g., at work or on an airplane). Individuals who smoke and other individuals who use nicotine are likely to find that they use up their supply of cigarettes or other nicotine-containing products faster than originally intended. Although over 80% of individuals who smoke express a desire to stop smoking and 35% try to stop each year, less than 5% are successful in unaided attempts to quit. Spending a great deal of time in using the substance is best exemplified by chain-smoking. Because nicotine sources are readily and legally available, spending a great deal of time attempting to procure nicotine would be rare. Giving up important social, occupational, or recreational activities can occur when an individual forgoes an activity because it occurs in smoking-restricted areas. Continued use despite knowledge of medical problems related to smoking is a particularly important health problem (e.g., an individual who continues to smoke despite having a tobacco-induced general medical condition such as bronchitis or chronic obstructive lung disease).

Specifiers

The following specifiers may be applied to a diagnosis of Nicotine Dependence (see p. 179 for more details):

With Physiological Dependence
Without Physiological Dependence

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Early Full Remission
Early Partial Remission
Sustained Full Remission
Sustained Partial Remission
On Agonist Therapy

Nicotine-Induced Disorder

292.0 Nicotine Withdrawal

Also refer to the text and criteria for Substance Withdrawal (see p. 184). The essential feature of Nicotine Withdrawal is the presence of a characteristic withdrawal syndrome that develops after the abrupt cessation of, or reduction in, the use of nicotine-containing products following a prolonged period (at least several weeks) of daily use (Criteria A and B). The withdrawal syndrome includes four or more of the following: dysphoric or depressed mood; insomnia; irritability, frustration, or anger; anxiety; difficulty concentrating; restlessness or impatience; decreased heart rate; and increased appetite or weight gain. The withdrawal symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning (Criterion C). The symptoms must not be due to a general medical condition and are not better accounted for by another mental disorder (Criterion D).

These symptoms are in large part due to nicotine deprivation and are typically more intense among individuals who smoke cigarettes than among individuals who use other nicotine-containing products. The more rapid onset of nicotine effects with cigarette smoking leads to a more intensive habit pattern that is more difficult to give up because of the frequency and rapidity of reinforcement and the greater physical dependence on nicotine. In individuals who smoke cigarettes, heart rate decreases by 5 to 12 beats per minute in the first few days after stopping smoking, and weight increases an average of 2–3 kg over the first year after stopping smoking. Mild symptoms of withdrawal may occur after switching to low-tar/nicotine cigarettes and after stopping the use of smokeless (chewing) tobacco, nicotine gum, or nicotine patches.

■ Diagnostic criteria for 292.0 Nicotine Withdrawal

A. Daily use of nicotine for at least several weeks.

B. Abrupt cessation of nicotine use, or reduction in the amount of nicotine used, followed within 24 hours by four (or more) of the following signs:
   (1) dysphoric or depressed mood
   (2) insomnia
   (3) irritability, frustration, or anger
   (4) anxiety
   (5) difficulty concentrating

(continued)

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☐ **Diagnostic criteria for 292.0 Nicotine Withdrawal** (*continued*)

(6) restlessness
(7) decreased heart rate
(8) increased appetite or weight gain

C. The symptoms in Criterion B cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

D. The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.

Additional Information on Nicotine-Related Disorders

Associated Features and Disorders

Associated descriptive features and mental disorders. Craving is an important element in Nicotine Withdrawal and may account for the difficulty that individuals have in giving up nicotine-containing products. Other symptoms associated with Nicotine Withdrawal include a desire for sweets and impaired performance on tasks requiring vigilance. Several features associated with Nicotine Dependence appear to predict a greater level of difficulty in stopping nicotine use: smoking soon after waking, smoking when ill, difficulty refraining from smoking, reporting the first cigarette of the day to be the one most difficult to give up, and smoking more in the morning than in the afternoon. The number of cigarettes smoked per day, the nicotine yield of the cigarette, and the number of pack-years also are related to the likelihood of an individual stopping smoking. Nicotine Dependence is more common among individuals with other mental disorders. Depending on the population studied, from 55% to 90% of individuals with other mental disorders smoke, compared to 30% in the general population. Mood, Anxiety, and other Substance-Related Disorders may be more common in individuals who smoke than in those who are ex-smokers and those who have never smoked.

Associated laboratory findings. Withdrawal symptoms are associated with a slowing on EEG, decreases in catecholamine and cortisol levels, rapid eye movement (REM) changes, impairment on neuropsychological testing, and decreased metabolic rate. Smoking increases the metabolism of many medications prescribed for the treatment of mental disorders and of other substances. Thus, cessation of smoking can increase the blood levels of these medications and other substances, sometimes to a clinically significant degree. This effect does not appear to be due to nicotine but rather to other compounds in tobacco. Nicotine and its metabolite cotinine can be measured in blood, saliva, or urine. Persons who smoke also often have diminished pulmonary function tests and increased mean corpuscular volume (MCV).

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Associated physical examination findings and general medical conditions. Nicotine Withdrawal may be associated with a dry or productive cough, decreased heart rate, increased appetite or weight gain, and a dampened orthostatic response. The most common signs of Nicotine Dependence are tobacco odor, cough, evidence of chronic obstructive pulmonary disease, and excessive skin wrinkling. Tobacco stains on the fingers can occur but are rare. Tobacco use can markedly increase the risk of lung, oral, and other cancers; cardiovascular and cerebrovascular conditions; chronic obstructive and other lung diseases; ulcers; maternal and fetal complications; and other conditions. Although most of these problems appear to be caused by the carcinogens and carbon monoxide in tobacco smoke rather than by nicotine itself, nicotine may increase the risk for cardiovascular events. Those who have never smoked but are chronically exposed to tobacco smoke appear to be at increased risk for conditions such as lung cancer and heart disease.

Specific Culture, Age, and Gender Features

The prevalence of smoking is decreasing in most industrialized nations, but is increasing in the developing areas. In the United States, the prevalence of smoking is slightly higher in males than in females; however, the prevalence of smoking is decreasing more rapidly in males than in females. In other countries, smoking is often much more prevalent among males.

Prevalence

In the United States, approximately 45% of the general population have never smoked. The remainder fall into one or more of the following categories: 25% are ex-smokers, 30% currently smoke cigarettes, 4% use pipes or cigars, and 3% use smokeless tobacco. In the United States, the prevalence of smoking has been decreasing approximately 0.7%–1.0% per year. The lifetime prevalence of Nicotine Dependence in the general population is estimated to be 20%. In the United States, between 50% and 80% of individuals who currently smoke have Nicotine Dependence. Lifetime prevalence of Nicotine Withdrawal among persons who smoke appears to be about 50%. Prospectively, it is estimated that about 50% of those who quit smoking on their own and about 75% of those in treatment programs experience Nicotine Withdrawal when they stop smoking.

Course

Smoking usually begins in the early teens. How quickly dependence develops is unclear. Among those who continue to smoke through age 20 years, 95% become regular, daily smokers. Of those who successfully quit, less than 25% quit on their first attempt. Most individuals who smoke have 3–4 failures before they stop smoking for good. In the United States, about 45% of those who have ever smoked eventually stop smoking. Withdrawal symptoms can begin within a few hours of cessation, typically peak in 1–4 days, and last for 3–4 weeks. Depressive symptoms postcessation may be associated with a relapse to smoking. Whether other Nicotine Withdrawal symptoms play a major role in relapse to smoking is debatable. Increased hunger and weight gain often persist for at least 6 months. Six months postcessation, 50% of individuals who have quit smoking report having had a desire for a cigarette in the last 24 hours.

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/

Familial Pattern

The risk for smoking increases threefold if a first-degree biological relative smokes. Twin and adoption studies indicate that genetic factors contribute to the onset and continuation of smoking, with the degree of heritability equivalent to that observed with Alcohol Dependence.

Differential Diagnosis

For a general discussion of the differential diagnosis of Substance-Related Disorders, see p. 190.

The symptoms of Nicotine Withdrawal overlap with those of **other substance withdrawal syndromes; Caffeine Intoxication; Anxiety, Mood,** and **Sleep Disorders; and medication-induced akathisia.** Admission to smoke-free inpatient units can induce withdrawal symptoms that might mimic, intensify, or disguise other diagnoses. Reduction of symptoms associated with the resumption of smoking or nicotine-replacement therapy confirms the diagnosis.

Because regular nicotine use does not appear to impair mental functioning, Nicotine Dependence is not readily confused with other Substance-Related Disorders and mental disorders.

292.9 Nicotine-Related Disorder Not Otherwise Specified

The Nicotine-Related Disorder Not Otherwise Specified category is for disorders associated with the use of nicotine that are not classifiable as Nicotine Dependence or Nicotine Withdrawal.

Opioid-Related Disorders

The opioids include natural opioids (e.g., morphine), semisynthetics (e.g., heroin), and synthetics with morphine-like action (e.g., codeine, hydromorphone, methadone, oxycodone, meperidine, fentanyl). Medications such as pentazocine and buprenorphine that have both opiate agonist and antagonist effects are also included in this class because their agonist properties produce similar physiological and behavioral effects. Opioids are prescribed as analgesics, anesthetics, antidiarrheal agents, or cough suppressants. Heroin is one of the most commonly abused drugs of this class and is usually taken by injection, although it can be smoked or "snorted" when very pure heroin is available. Fentanyl is injected, whereas cough suppressants and antidiarrheal agents are taken orally. The other opioids are taken both by injection and orally.

This section contains discussions specific to the Opioid-Related Disorders. Texts and criteria sets have already been provided for the generic aspects of Substance Dependence (p. 176) and Substance Abuse (p. 182) that apply across all substances. Texts specific to Opioid Dependence and Abuse are provided below; however, there are no additional specific criteria sets for Opioid Dependence or Opioid Abuse. Specific text and criteria

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Hoskins vs RJ Reynolds et al

Sept 97	record review	14 hrs
Oct 1-13	review + report prep	12 hrs 26 hrs to 10/13
Nov 1-12	review	5 hrs 31 hrs to 11/12

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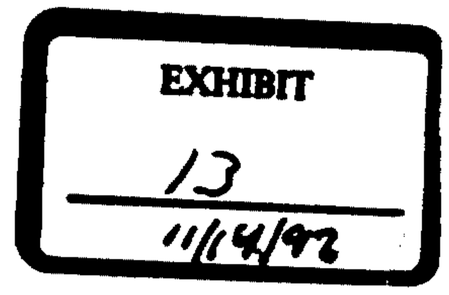
EXHIBIT
12
11/14/97

http://legacy.library.ucsf.edu/tid/plr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/dqvl0001

Chamberlain vs. RJ Reynolds et al

April 97	review & prep report	12 hrs
Sept 97	review	8 hrs
Oct 97	review	4 hrs
Nov 1-12, 97	review records	8 hrs
		32 hrs to 11/12

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http://legacy.library.ucsf.edu/tid/plr07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/ytxl0001